TITLE: Use of Patient Information in the Conduct of Research Activities

APPLIES TO: Visiting Nurse Service of New York Home Care II d/b/a VNS Health Home Care; New Partners, Inc. d/b/a VNS Health Personal Care; Visiting Nurse Service of New York Hospice Care d/b/a VNS Health Hospice Care; VNS CHOICE d/b/a VNS Health Health Plans; VNS Health Behavioral Health, Inc., and Medical Care at Home, P.C. (each a "VNS Health Covered Entity").

POLICY OWNER: Corporate Compliance Department

FIRST ISSUED: Conditionally Approved on September 23, 2013

NUMBER: HIPAA.5

PURPOSE

Each VNS Health Covered Entity complies with all applicable requirements of the Health Insurance Portability and Accountability Act of 1996, as amended by the Health Information Technology for Economic and Clinical Health Act, Title XIII of the American Recovery and Investment Act of 2009 and their implementing regulations, as amended from time to time (collectively, "HIPAA"). Each VNS Health Covered Entity must ensure that human research projects conducted or proposed by the VNS Health Covered Entity are conducted in compliance with HIPAA. This Use of Patient Information in the Conduct of Research Activities policy (the "Policy") ensures all research activities comply with HIPAA.

The VNS Health IRB serves as the institutional review board for each VNS Health Covered Entity, and may take the actions required by it hereunder. This Policy applies to both internal researchers who are employed by VNS Health and its subsidiaries and affiliates, as well as external researchers affiliated with other organizations.

POLICY AND PROCEDURE

A. General Application of HIPAA to Research.[1] HIPAA applies to all research studies that involve the use or disclosure of individually identifiable protected health information ("PHI"). Moreover, unlike the Common Rule[2], HIPAA applies regardless of the source of funding for the research. Research studies affected by HIPAA include: (i) record research (i.e., research using previously existing PHI, such as research involving a review of previously created medical records) (ii) research involving primary data collection, such as interviews and surveys with patients/members, and (iii) research involving treatment[3] of research participants, such as clinical trials.

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[1] **Note**: Research is defined, under HIPAA, as systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. 45 CFR § 164.501.

[2] **Note**: The Common Rule is HIPAA's term for the Federal Policy for the Protection of Human Subjects, including 10 CFR Part 745, 14 CFR Part 1230, 15 CFR Part 27, 16 CFR Part 1028, 21 CFR Part 56, 22 CFR Part 225, 24 CFR Part 60, 28 CFR Part 46, 32 CFR Part 219, 34 CFR Part 97, 38 CFR Part 16, 40 CFR Part 26, 45 CFR Part 46, Subpart A, 45 CFR Part 690, and 49 CFR Part 11.

[3] **Note**: Treatment is defined, under HIPAA, as the provision, coordination, or management of health care and related services by one or more health care providers, including (i) coordination or management of health care by a health care provider with a third party, (ii) consultation between health care providers relating to a patient, or (iii) the referral of a patient for health care from one health care provider to another. 45 CFR § 164.501.

When an investigator conducts a research study that is subject to both HIPAA and the Common Rule, the investigator must comply with the regulations under both laws. Additionally, where applicable, a research study must also comply with the Federal Food & Drug Administration's ("FDA's") human subjects protection regulations.[4]

As a general rule, e ach VNS Health Covered Entity requires that any investigator conducting such a research study involving the use or disclosure of PHI must ensure the receipt of a HIPAA authorization from each research participant prior to using or disclosing PHI for research purposes unless one of the following five exceptions ("Exceptions") exists, as discussed in more detail below:

1. the investigator is only conducting a review preparatory to future research;

2. the research study uses only PHI of deceased individuals;

3. the investigator uses only a "limited data set" in conducting the research study and obtains a "data use agreement"[5] from all recipients of the limited data set (*see* HIPAA.4 – De-Identifying and Re-Identifying Patient/Member Health Information and Creation of Limited Data Sets, for a discussion on limited data sets);

4. the investigator uses only "de-identified" PHI in conducting the research study (*see* HIPAA.4 – De-Identifying and Re-Identifying Patient/Member Health Information and Creation of Limited Data Sets, for a discussion on de-identified PHI); or

5. the investigator obtains approval for a waiver or alteration of a waiver of authorization from the VNS Health IRB prior to commencing the research study.

Note: If the research involves a clinical intervention of the patient, the patient will also need to receive a copy of the Joint HIPAA Notice of Privacy Practices of the VNS Health Organized Health Care Arrangement (OHCA) and sign an acknowledgment, where applicable, as discussed in **Section F** below.

Each VNS Health Covered Entity also requires that, whenever PHI is being used or disclosed for research purposes pursuant to an Exception, the investigator must comply with VNS Health's HIPAA.7 Minimum Necessary Rule policy. In order to comply with the minimum necessary requirements, the investigator must make reasonable efforts to limit the uses and disclosures of, and requests for, PHI to the minimum necessary to accomplish the purpose(s) of the research study.

B. Research Authorization. In those instances where an investigator's research study does not fit into one of the Exceptions, and the investigator intends to use or disclose PHI during the conduct of their research study, the investigator must ensure that a valid, executed authorization is obtained from each research participant or their legally authorized representative (referred to as a "personal representative" under HIPAA; *see* HIPAA.16 – Disclosures to Family Members, Friends and Personal Representatives). All research authorizations must be approved by the VNS Health IRB during the VNS Health IRB's initial review of the investigator's research request (as discussed in Section E below) and must, whenever possible, be the authorization attached hereto as Exhibit A. If the research protocol is

[4] *See* 21 CFR Parts 50 and 56.
[5] **Note**: VNS Health has two different data use agreement forms – one for internal VNS Health researchers and one for external researchers.

not subject to IRB review (e.g., research that falls within one of the Common Rule's categories of "exempt" research), the VNS Health IRB will review the research protocol solely for privacy issues.

1. Requirements for All Authorizations. All research authorizations must be written in plain language and contain at least the following:

(a) A meaningful and specific description of the PHI to be used and disclosed in the research study;

(b) A list of all persons (or classes of persons) who may use or disclose the PHI;

(c) A list of the persons (or classes of persons) to whom the PHI may be disclosed;

(d) The expiration date or event of the authorization. For research purposes this statement can be "end of the research" or "none" (especially with respect to the creation and maintenance of research data bases or repositories);

(e) A statement that the research participant has a right to revoke the authorization at any time in writing and a description of how to revoke the authorization;

(f) A statement noting that used or disclosed PHI may be subject to re-disclosure and no longer protected by HIPAA;

(g) The signature and date of the research participant or their authorized representative. If signed by an authorized representative, a statement of such representative's authority to act for the research participant;

(h) A statement of each purpose of the use or disclosure of the PHI. If authorization is for future research, however, it is sufficient to describe that purpose such that it would be reasonable for the participant to expect their information could be used or disclosed for future research. This purpose description could include specific statements regarding sensitive research, if applicable; and

(i) For research not involving research-related treatment, a statement that the research subject has right to refuse to sign the authorization without being denied treatment, payment, enrollment or eligibility for benefits.

The authorization should be included in the research participant's study record, and each research participant should be provided with an executed copy. An authorization that includes future research may also include information collected beyond the time of the original research study.

2. For Studies which Include Treatment. Where the research study is being conducted in connection with research-related treatment of the research participant, the research authorization may contain a statement that provision of the research-related treatment is conditioned on the research participant executing the authorization.

Where a research study includes treatment or repeated data collection over time, the research participant can be denied the right to access the PHI obtained in the course of that trial (the "Research Information"). In order to deny the research participant access to Research Information:

(a) The research authorization must contain a statement informing the research participant that they will be denied access to the Research Information during the course of the clinical trial;

(b) The research participant must agree to the denial of access to Research Information when they consent to participation in the research as indicated by their signature or the signature of their legally authorized representative, as applicable, on the authorization ; and

(c) The research must be ongoing when the research participants request access.

The research participant must also be advised of their right to be provided access to the Research Information once the research is completed. The investigation must, however, maintain a high level of ethical consideration for the welfare of the research participants and provide access in the appropriate circumstances.

While conducting the research, the investigator must comply with the limited scope of permissible uses and disclosures for the Research Information. Additionally, the investigator will be allowed to disclose PHI as relevant to the trial, including disclosure to public health agencies, health oversight agencies and persons required or directed to report information to the FDA. Any parties receiving disclosures of PHI should be listed in the HIPAA authorization.

Unless an investigator is conducting a review preparatory to a research study or has been approved for one of the other authorization "Exceptions" (discussed below), they must obtain an authorization prior to reviewing previously collected PHI in connection with treatment to determine an individual's eligibility for participation in research. Alternatively, an investigator may obtain a partial waiver of authorization from the IRB to permit the research recruitment to take place. Because each VNS Health Covered Entity can disclose PHI to the individual who is the subject of the PHI, it may discuss the option of enrolling in a research study without first obtaining a research authorization or IRB waiver of authorization. Once the PHI needs to be disclosed to an external investigator for the purposes of recruitment into the research study, each VNS Health Covered Entity or internal VNS Health study staff from another VNS Health Division must either obtain an authorization or waiver of authorization (as discussed in Section E below).

3. Compound Authorizations. Generally, an authorization for the use or disclosure of PHI in a research study may be combined to create a compound authorization with any other type of written permission needed for the same or another research study, including:

(a) an informed consent; or

(b) a written authorization to use or disclose PHI for such research.

Additionally, a research authorization may be combined with an authorization for a different purpose (except for an authorization for the disclosure of psychotherapy notes), except if a VNS Health Covered Entity has conditioned the provision of treatment, payment, enrollment in a health plan or eligibility for benefits on the provision of one of the authorizations, such as conditioning the provision of research-related treatment on one of the authorizations. If a VNS Health Covered Entity has conditioned the provision of research-related treatment on the provision of one of the authorizations, the compound authorization must clearly differentiate between conditioned and unconditioned components and provide the research participant the option to opt-in to the research activities described in the unconditioned authorization. The opt-in could be accomplished as follows:

(a) by a separate check-box for the unconditioned research activity to indicate whether the participant has opted-in to the unconditioned research activity, while maintaining one signature line for the authorization.

(b) by a separate signature line for the unconditioned authorization in addition to the signature for the conditioned research.

A compound authorization may cross-reference relevant sections of the authorization for both conditioned and unconditioned research to minimize repeating sections of the authorization.

Additionally, if it is clear that an individual is revoking only one part of a compound authorization, such revocation will not require the revocation of the entire authorization. However, if it is not clear which research activities are being revoked, the participant needs to provide further written specific instruction regarding the limited nature of the revocation or the assumption should be authorization for all of the research is being revoked. As with any other revocation, the information and revocation must be retained and documented in a manner that will ensure appropriate discontinuance of uses and disclosures of PHI (except to the extent the investigators have already acted in reliance on the authorization, which would permit certain limited, continued use and disclosure, as necessary to maintain the integrity of the research study.)

For further discussion of compound authorizations, see HIPAA. 14 &15 Policy on Uses and Disclosures of Member/Patient Information policies. Aside from the combined authorization attached as Exhibit B for conditioned and unconditioned research, for Covered Entity purposes, a research authorization should only be combined in special circumstances as specifically approved by the IRB in connection with their review of the proposed research study, as discussed below in Section G.

C. Review Preparatory to Future Research. An internal investigator can conduct a review of PHI in preparation for future research without first obtaining a research authorization. Before conducting any preparatory review, the investigator will obtain approval from the VNS Health IRB as described in this Section. All preparatory review requests must be made in writing to the VNS Health IRB. Before approving any preparatory review request, the VNS Health IRB (serving on behalf of the Covered Entity) must obtain from the investigator a written and signed document containing the following representations:

1. The use and disclosure of the PHI is necessary to the future research.

2. The PHI will be reviewed solely for the narrow purpose of preparing for the future research.

3. No PHI will be removed from a VNS Health Covered Entity by the investigator in the course of the preparatory review (although information can be recorded in "de-identified" form). The investigator may photocopy or write down relevant portions of the record or the necessary PHI so long as such photocopy or written notes are not removed from the VNS Health Covered Entity. Note that if a VNS Health Covered Entity works directly with an external investigator, the VNS Health Covered Entity should obtain a waiver of authorization, instead of relying on the review preparatory to future research exception.

4. The purpose of each preparatory review shall be either to aid in the development of a research hypothesis, assess the population of interest or scope of an issue and/or to aid the recruitment of research participants. All approvals of preparatory research shall be documented, and if the preparatory review results in a disclosure of PHI (such as when an investigator who is not a member of the VNS Health Covered Entity workforce or from another VNS Division comes onsite to the VNS Health Covered Entity to conduct a review preparatory to research), it shall be tracked and documented as a disclosure in accordance with the HIPAA.11 VNS Health Accounting for Disclosure of Patient and Member Information policy, and the Chief Compliance & Privacy Officer ("Privacy Officer") should be notified. Each VNS Health Covered Entity will rely on representations of the investigator that the review is being conduct solely in preparation for a research study.

D. Research Involving a Deceased Individual. An investigator can use and disclose PHI of a deceased person for research purposes without first obtaining a research authorization. Before conducting any such research study, however, the investigator must obtain approval from the VNS Health IRB. All such research requests shall be made in writing to the IRB and shall contain a written and signed document from the investigator containing the following representations:

1. The use and disclosure of the PHI contained in the medical records is necessary for research purposes.

2. The use or disclosure is sought solely for research of PHI of deceased persons.

Before approving any such research request, VNS Health IRB may request, but is not required to request, documentation of the death of each research subject from the investigator. All approvals of research studies involving deceased persons shall be documented and each disclosure of an individual's PHI shall be tracked and documented in accordance with HIPAA.11 VNS Health Accounting for Disclosure of Patient and Member Information policy, and the Privacy Officer should be contacted.

E. Alteration or Waiver of Authorization. An investigator may obtain an alteration or waiver of the authorization requirement for the use and disclosure of PHI from the VNS Health IRB. A request for an alteration or waiver must be in writing to the VNS Health IRB. In connection with a request for approval of an alteration or a waiver of the authorization requirement for proposed research, the VNS Health IRB shall consider whether the proposed research study satisfies the following criteria:

1. The use or disclosure of PHI will involve no more than a minimal risk to the privacy of the research participants based on the presence of the following elements:

   (a) An adequate plan exists to protect the identifiers from improper use and disclosure;

   (b) An adequate plan exists to destroy the identifiers at the earliest opportunity

consistent with conduct of the research unless there is a health or research justification that makes retention necessary or such retention is otherwise required by law; and

(c) There are adequate written assurances that the PHI will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the proposed research, or for other research for which use or disclosure of individually identifiable health information is permitted by HIPAA.

2. The proposed research study could not practicably be conducted without waiver or alteration of authorization.

3. The proposed research study could not practicably be conducted without access to and use of the PHI.

4. Upon any approval of an alteration or waiver request, the VNS Health IRB, as applicable, shall prepare a written approval statement which:

(a) identifies the VNS Health IRB;

(b) indicates the approval date;

(c) states that the IRB has determined the alteration or waiver of authorization for the proposed research study satisfies all the criteria listed above;

(d) provides a brief description of the PHI for which use or access has been determined by the IRB to be necessary; and

(e) specifies whether action was taken by the VNS Health IRB under normal or expedited review procedures.

This written approval statement must be signed by the chairman of the VNS Health IRB or their designee.

If the VNS Health IRB regularly approves conducting research through the waiver of the authorization requirement and, as a result, each VNS Health Covered Entity routinely uses and discloses PHI for research purposes without obtaining an authorization pursuant to this exception, then the Joint HIPAA Notice of Privacy Practices of the VNS Health OHCA must advise patients/members of this practice.

F. **HIPAA Notice**. HIPAA requires that each patient/member receive a written notice, known as the Joint HIPAA Notice of Privacy Practices of the VNS Health OHCA, that describes each VNS Health Covered Entity's privacy practices, the patient's/member's individual rights under HIPAA, and the uses and disclosures of PHI made by each VNS Health Covered Entity. Where a patient/member participating in a research study is receiving treatment, investigators must use the Joint HIPAA Notice of Privacy Practices of the VNS Health OHCA form. Each investigator will also make a good faith attempt to obtain an acknowledgment of the privacy notice from the research participant prior to commencing treatment, if the VNS Health Covered Entity has not already received the research participant's acknowledgement of the privacy notice in connection with other treatment activities. If this acknowledgment does not cover the investigator because he or she is providing treatment activities outside of his or her role as a member of

the relevant VNS Health Covered Entity workforce, the investigator should obtain a separate acknowledgment as well acknowledging receipt of the relevant notice of privacy practices. In either case, where the investigator cannot obtain an acknowledgment executed by the participant in the clinical trial, the investigator must document such failure in the appropriate medical record, along with the reason for the failure (e.g., the research participant refused to execute the acknowledgment).

G. IRB.

1. In connection with HIPAA, the VNS Health IRB must include in its review of each research request, a review of each of the following, where applicable, (i) the research authorization, (ii) the Joint HIPAA Notice of Privacy Practices of the VNS Health OHCA and acknowledgment, (iii) requests for the alteration or waiver of authorization, (iv) requests to conduct preparatory research reviews; (v) methods of creating a limited data set or de- identifying PHI; (vi) a data use agreement; and (vii) requests to conduct research involving a deceased individual's PHI. Whenever possible, the VNS Health IRB will ensure that an investigator use the form of research authorization attached hereto as Exhibit A and the Joint HIPAA Notice of Privacy Practices of the VNS Health OHCA and acknowledgment approved by each VNS Health Covered Entity. Additionally, in all circumstances where an investigator desires to use a compound authorization, such authorization will be separately considered by the VNS Health IRB. For HIPAA purposes, each VNS Health Covered Entity will rely on the VNS Health IRB's representation that a research protocol meets HIPAA's documentation and minimum necessary requirements (where applicable).

H. Training. All members of the research workforce [6] of each VNS Health Covered Entity shall participate in a HIPAA training program. The HIPAA training program for members of the research workforce of each VNS Health Covered Entity will include both HIPAA basics training and research specific training. HIPAA basics training covers general privacy and general security requirements under HIPAA.

1. Research Specific Training. The research specific portion of the HIPAA training for the research workforce must include:

(a) The research specific HIPAA rules and processes discussed under this Policy;

[6] The research workforce must include all investigators, data processors, research staff and others who are employed by the Covered Entity who conduct research and/or who handle research documentation or information.

(b) Policies and procedures for the management of information collected by the research workforce when conducting research;

(c) Compliance procedures;

(d) Policies and procedure for the maintenance of research information, including both paper and computer electronic records; and

(e) Policies and procedures regarding computer security.

2. IRB . Members of the VNS Health IRB will undergo the same training as the researchers. In addition, they will be trained in their specific responsibilities under HIPAA, including:

(a) The specific elements of a HIPAA authorization;

(b) The necessary additions to consents and notices under HIPAA;

(c) The elements to be reviewed when considering an alteration or waiver of authorization;

(d) The other exceptions to authorization including reviews preparatory to research and research involving deceased individuals;

(e) The steps necessary to "de-identify" information under HIPAA; and

(f) The steps necessary to create a "limited data set" for research purpose and the requirements of a data use agreement.

I. Prohibition of Sale of PHI. HIPAA's prohibition on the sale of PHI does not include payments received in the form of grants, or contracts or other arrangements to perform research study. Thus, a research sponsor's payment to a VNS Health Covered Entity to conduct a research study is not considered a sale of PHI, even if (i) the results of the research include PHI and are disclosed to the sponsor as part of the study or (ii) the sponsor's payment is conditional on the VNS Health Covered Entity reporting PHI.

A sale of PHI does exist, however, if a VNS Health Covered Entity is primarily being compensated to supply PHI it maintains in its role as a VNS Health Covered Entity as opposed to receiving compensation for research activities. For example, each VNS Health Covered Entity's disclosure of PHI to a third-party researcher that is conducting the research in exchange for compensation is a sale of PHI, unless it can be shown that the only compensation being received is a reasonable, cost-based fee to cover the cost to prepare and transmit the PHI/data for such purposes. This cost-based fee may include both direct and indirect costs of preparing and transmitting the data, including (i) labor, materials, and supplies used in generating, storing, retrieving, and transmitting the PHI, (ii) labor and supplies used to ensure the PHI is disclosed in a permissible manner, and (iii) capital and overhead costs incurred in connection with subsections (i) and (ii).

If the fee charged allows a party involved in the research to incur a profit from the disclosure of the PHI, then the fee will not be considered a research cost-based fee. In any instance where a fee is received in exchange for the sale of PHI in connection with research and the fee cannot be

shown to meet the foregoing exception, the authorization must contain a disclosure detailing that such payment is being received in exchange for the sale of PHI.

For a discussion of authorizations where a VNS Health Covered Entity seeks an individual's written legal permission to obtain PHI about the individual from another covered entity that maintains the PHI, see HIPAA. 15- VNS Health Provider Policy on Use and Disclosure of Patient Information and HIPAA.14 – VNS Health Health Plan's Policy on Use and Disclosure of Member Information policies.

J. Accounting for Research Disclosures. Research disclosures made pursuant to an individual's authorization and disclosures of limited data sets to researchers with a data use agreement are exempt from the accounting of disclosures requirement. In addition, for disclosures of PHI for research purposes without the individual's authorization that involve at least 50 records, each VNS Health Covered Entity may provide a simplified accounting of such disclosures by providing individuals with a list of all protocols for which their PHI may have been disclosed pursuant to this Policy, as well as the researcher's name and contact information.

REFERENCE: 45 CFR 164.512(i), 164.512(a-c), 508; 21 CFR parts 50 & 56; 45 CFR 164.528(b)(4)

Reviewed:		1/2015	11/2016	4/2018	10/2019	10/2020	05/2022	3/2023
Revised & Approved:	9/2013		11/2016	1/2019	1/2020	3/2021	10/2022	3/2023
Reviewed:	6/2023							
Revised & Approved:	9/2023							

VNS Health

EXHIBIT A

Authorization (Permission) to Use or Disclose (Release)
Identifiable Health Information for Research Purposes

Participant's Name: _____

Birth Date: _____

1. **What is the purpose of this form?**

Researchers at [insert relevant VNS Health Covered Entity] (the "VNS Health Covered Entity") would like to use for research purposes your health information that is held or collected by VNS Health Covered Entity ("Health Information"). Your Health Information may contain "protected health information" ("PHI") as defined under the Health Insurance Portability and Accountability Act of 1996, and its implementing regulations, as amended (collectively, "HIPAA"). HIPAA requires VNS Health Covered Entity to obtain your authorization to use or disclose PHI for research purposes in most cases. Please carefully review this authorization. If you agree that researchers can use your Health Information, you must sign and date this form to give them your permission. Your authorization is voluntary.

Section A: (must be completed)

2. **Why do the researchers want to use and disclose your Health Information?**

[Covered Entity] will collect your Health Information and share it with if you enter this research study. [Investigator] will use your Health Information in the research study. This study is titled _____. The purpose of this study is to_____.

3. **What Health Information do the researchers want to use and disclose?**

The researchers want to copy and use the portions of your medical record that they will need for their research. If you enter the research study, Health Information that will be used and/or released may include the following:

_____
_____
_____
_____
_____
_____
_____
_____

4. **Who will be able to use and disclose your Health Information?**

[VNS Health Covered Entity] will use your Health Information for research. As part of this research, they may give your Health Information to the following groups taking part in, or overseeing, the research. [VNS Health Covered Entity] may also permit the following groups to come in to review your original records that are kept by [VNS Health Covered Entity] so that they can monitor their research study:

_____

_____

_____

_____

_____

_____

_____

_____

Section B: (to be completed ONLY if this authorization is for research which includes treatment)

5. **What happens if you do not sign this authorization?**

If you do not sign this authorization, you will not be able to take part in the research study described in this authorization for which you are being considered. Your participation in the research referenced by this authorization is conditioned upon your execution of this research authorization.

6. **What are your rights regarding access to your Health Information?**

You have the right to refuse to sign this authorization form. You have the right to review and/or copy records of your Health Information kept by [VNS Health Covered Entity]. However, while the research study described in this authorization is ongoing, [VNS Health Covered Entity] or [Investigator] may refuse to permit you access to your Health Information obtained in the course of the research study. You will be granted access to this Health Information following the completion of the research study.

Section C: (must be completed)

7. **How will information about you be kept private?**

[Investigator] will not release Health Information about you to others except as authorized or required by law. However, once your Health Information is given to other organizations that are not required to follow HIPAA, it may no longer be subject to HIPAA and may be subject to re-disclosure by those organizations.

8. **If you sign this form, will you automatically be entered into the research study?**

No, you cannot be entered into any research study without further discussion and separate consent. After discussion, you may decide to take part in the research study. At that time, you will be asked to sign a specific research consent form.

9. **What happens if you want to withdraw your permission?**

You can change your mind at any time and withdraw your permission to allow your Health Information to be used in the research. If this happens, you must withdraw your permission in writing. Beginning on the date you withdraw your permission, no new Health Information will be used for the research that you are withdrawing from. However, researchers may continue to use the Health Information that was provided before you withdrew your permission.

If you sign this form and enter the research study, but later change your mind and withdraw your permission, you will be removed from the research study activity for which you are withdrawing permission at that time.

To withdraw your permission, please contact the VNS Health Privacy Officer at hipaaandprivacy.team@vnshealth.org. He/she will make sure your request to withdraw your permission is processed correctly.

10. **How long will this permission last?**

If you agree by signing this form that researchers can use your Health Information, this permission [expires upon_____] [has no expiration date]. However, as stated above, you can change your mind and withdraw your permission at any time.

[To be completed ONLY if for research not involving treatment and Section B has been removed.]

11. **If you refuse to participate in this research will it effect your treatment?**

You may refuse to sign this form and your health care and the payment for your health care will not be affected if you do not sign this form.

I hereby authorize the use and/or disclosure of my Health Information as described in this form. I understand that this authorization is voluntary.

Signature of research participant or research participant's representative	**Date**

(This form MUST be completed before signing.)

If this authorization is signed by a research participant's representative, please complete the following:

Print the name of research participant's representative: _____

Describe the representative's authority to act for the research participant:

_____

_____

Signature of Person Obtaining Permission: _____

Date: _____

Printed Name of Person Obtaining Permission: _____

YOU MAY REFUSE TO SIGN THIS AUTHORIZATION

VNS Health

Directions for Completing Authorization Form For Research

The Item numbers in these directions correspond to the Section and Item numbers in the research authorization.

Section A: This Section should be completed in all instances. This Section should reflect the health information to be used in the research study and the persons or entities that will have access to the information. It may be easier for each VNS Health Covered Entity or investigator conducting the research on behalf of the VNS Health Covered Entity (who are aware of the information and uses and disclosures necessary to perform the research study) to complete this Section. Where appropriate, the appropriate information can be inserted before the subject signs the consent. For example, the health information to be disclosed can be pre-printed on the form. However, the research subject should only execute the authorization when they are in full agreement with the information indicated.

2. Each VNS Health Covered Entity or investigator should provide a description of each purpose for which the health information will be used or/disclosed in the research study. The description should provide sufficient information to allow the research subject to make an informed decision as to whether to allow the release of the information; however, it should not be a broad or blanket statement requesting the use and/or disclosure for a wide range of unspecified purposes. If authorization is for future research, however, it is sufficient to describe that purpose such that it would be reasonable for the participant to expect his/her health information could be used or disclosed for future research. This purpose description could include specific statements regarding sensitive research, if applicable.

3. Each VNS Health Covered Entity or investigator should include the name or other specific identification of the persons or classes of persons who are authorized to use and/or disclose the health information being used in the research study. If a class of persons is listed, it should be specific enough so that the reader will know, with reasonable certainty, the individuals indicated. Please note this list should be as extensive as possible and include all persons that will be necessary over the entire research study because, once completed, only the persons listed are authorized to use and/or disclose the health information in the research study.

4. Each VNS Health Covered Entity or investigator should include a description of the information to be used or disclosed in the research study. The description should be specific enough to allow the reader to know exactly what information is being referenced. For example, the description could reference “all laboratory results for Mr. X” or “all laboratory results from the months July 1999 through September 1999 for Mr. X.” Please note this description should be as extensive as possible and include all information that will be necessary over the entire research study because, once completed, only the information described can be used in the research study. Please note, there is no limit on the information that can be authorized for disclosure and, therefore, if the research participant wishes to disclose his/her entire medical record, this fact can be indicated.

Section B: This Section should be completed only if the VNS Health Covered Entity is seeking authorization to use and/or disclose health information it created for the purpose of research that includes the treatment of the research subject.

5. This Item is only necessary if the VNS Health Covered Entity is conducting research which includes treatment and is seeking to condition such treatment on the research participant executing this authorization.

6. This Item is only necessary if the VNS Health Covered Entity is seeking an authorization in connection with a clinical trial involving treatment and wishes to limit the research participant's access to the information obtained in the course of the clinical trial.

Section C: This Section should be completed in all instances.

9. Each VNS Health Covered Entity or investigator should indicate how the research can be revoked and the specific person to which the revocation needs to be addressed.

10. Each VNS Health Covered Entity or investigator conducting the research on behalf of the VNS Health Covered Entity should complete the date or event upon which the authorization will expire. The expiration date or event should either be a specific date (e.g., December 20, 2003), a specific time period (e.g., one year from the date of signature) or an event directly relevant to the research participant or the purpose of the use or disclosure (e.g., for the duration of the research participant's participation in the research study). Alternatively, the statement "end of the research study," "none," or similar language is sufficient for all research, including the creation or maintenance of a research database or research repository.

11. If the research does not involve treatment, the VNS Health Covered Entity cannot condition patient treatment on execution of this authorization.

The research participant or research participant's representative should sign and date the authorization. If the authorization is completed by a research participant's representative, the representative should also print their name and describe their authority to act on behalf of the research participant at the bottom of this Section. Lastly, the research participant or research participant's representative should be provided with a copy of the executed authorization.

VNS Health

EXHIBIT B

Compound Authorization (Permission) to Use or Disclose (Release)
Identifiable Health Information for Research Purposes

Participant's Name: _____

Birth Date: _____

1. **What is the purpose of this form?**

Researchers at [insert relevant VNS Health Covered Entity] (the "VNS Health Covered Entity") would like to use for research purposes your health information that is held or collected by the VNS Health Covered Entity ("Health Information"). Your Health Information may contain "protected health information" ("PHI") as defined under the Health Insurance Portability and Accountability Act of 1996, and its implementing regulations, as amended (collectively, "HIPAA"). HIPAA requires VNS Health Covered Entity to obtain your authorization to use or disclose PHI for research purposes in most cases. Please carefully review this authorization. If you agree that researchers can use your Health Information, you must sign and date this form to give them your permission. Your authorization is voluntary.

Section A: (must be completed)

2. **Why do the researchers want to use and disclose your Health Information?**

[Covered Entity] will collect your Health Information and share it with the_____if you enter this research study. [Investigator] will use your Health Information in the_____research study. This study is titled _____. The purpose of this study is to _____.

3. **What Health Information do the researchers want to use and disclose?**

The researchers want to copy and use the portions of your medical record that they will need for their research. If you enter the research study, Health Information that will be used and/or released may include the following:

_____
_____
_____
_____
_____
_____
_____
_____
_____

You may request a blank copy of the data forms from the study doctor or his/her research staff to learn what information will be shared.

4. **Who will be able to use and disclose your Health Information?**

[VNS Health Covered Entity] will use your Health Information for research. As part of this research, they may give your Health Information to the following groups taking part in, or overseeing, the research. [VNS Health Covered Entity] may also permit the following groups to come in to review your original records that are kept by [VNS Health Covered Entity] so that they can monitor their research study**:**

5. **What happens if you do not sign this authorization?**

If you do not sign this authorization, you will not be able to take part in the research study described in this Section A for which you are being considered. Your participation in the research referenced by Section A of this authorization is conditioned upon your execution of this research authorization.

6. **What are your rights regarding access to your Health Information?**

You have the right to refuse to sign this authorization form. You have the right to review and/or copy records of your Health Information kept by [VNS Health Covered Entity]. However, while the research study described in this Section A is ongoing, [VNS Health Covered Entity] or [Investigator]___may refuse to permit you access to your Health Information obtained in the course of the research study. You will be granted access to this Health Information following the completion of the research study.

Section B: (must be completed)

7. **How will information about you be kept private?**

[Investigator] will keep all Health Information private to the extent possible, even though _____is not required to follow HIPAA. Only researchers working with [Investigator] or authorized by [VNS Health Covered Entity] will have access to your information.

[Investigator] will not release Health Information about you to others except as authorized or required by law. However, once your Health Information is given to other organizations that are not required to follow HIPAA, it may no longer be subject to HIPAA and may be subject to re-disclosure by those organizations.

8. **If you sign this form, will you automatically be entered into the research study?**

No, you cannot be entered into any research study without further discussion and separate consent. After discussion, you may decide to take part in the research study. At that time, you will be asked to sign a specific research consent form.

9. **What happens if you want to withdraw your permission?**

You can change your mind at any time and withdraw your permission to allow your Health Information to be used in the research. If this happens, you must withdraw your permission in writing. You may withdraw your permission to allow your Health Information to be used in (i) the research described in Section A above, (ii) the research described in Section C below, or (iii) all of the research described in this authorization, at any time by notifying the person indicated below in writing and indicating the specific aspects of this research you are withdrawing from. If you do not indicate specific research activities that you wish to withdraw from, we will withdraw you from all the research under this authorization.

Beginning on the date you withdraw your permission, no new Health Information will be used for the research that you are withdrawing from. However, researchers may continue to use the Health Information that was provided before you withdrew your permission.

If you sign this form and enter the research study, but later change your mind and withdraw your permission, you will be removed from the research study activity for which you are withdrawing permission at that time. To withdraw your permission, please contact the VNS Health Privacy Officer at hipaaandprivacy.team@vnsny.org. He/she will make sure your request to withdraw your permission is processed correctly.

10. **How long will this permission last?**

If you agree by signing this form that researchers can use your Health Information, this permission [expires] upon_____] [has no expiration date]. However, as stated above, you can change your mind and withdraw your permission at any time.

Section C: (optional for any additional unconditioned research and may be duplicated for other additional unconditioned research)

You may refuse to agree to participate in the research described in this Section C and your health care and payment for health care will not be affected nor will your ability to participate in the research described in Section A above. All of the information in Section B above applies to this research as well.

11. **Why do the researchers want your Health Information?**

[VNS Health Covered Entity] will collect your Health Information and share it with the_____if you enter this research study. [Investigator] will use your information in_____research study. This study is titled_____. The purpose of this study is to _____.

12. **What Health Information do the researchers want to use?**

The researchers want to copy and use the portions of your medical record that they will need for their research. If you enter the research study, information that will be used and/or released may include the following:

_____
_____
_____
_____
_____
_____
_____
_____
_____

You may request a blank copy of the data forms from the study doctor or his/her research staff to learn what information will be shared.

13. **Who will be able to use your Health Information?**

[VNS Health Covered Entity] will use your Health Information for research. As part of this research, they may give your information to the following groups taking part in the research. [VNS Health Covered Entity] may also permit the following groups to come in to review your original records that are kept by [VNS Health Covered Entity] so that they can monitor their research study:

_____
_____
_____
_____
_____
_____

_____

14. **What are your rights regarding access to your Health Information?**

You have the right to refuse to agree to participate in the research described in this Section C. If, however, you initial below, you are agreeing to participate in the research in this Section C. If you do not initial you will not participate in the research set forth in this Section C. You further understand that whether or not you initial this Section, it will not affect your participation in the other research described in this authorization or another treatment at the [Covered Entity].

Initial Here: _____

VNS Health

I hereby authorize the use and/or disclosure of my Health Information as described in this form. I understand that this authorization is voluntary.

Signature of research participant or research participant's representative	Date

(This form MUST be completed before signing.)

If this authorization is signed by a research participant's representative, please complete the following:

Print the name of research participant's representative: _____

Describe the representative's authority to act for the research participant:

_____

_____

Signature of Person Obtaining Permission: _____

Date: _____

Printed Name of Person Obtaining Permission: _____

YOU MAY REFUSE TO SIGN THIS AUTHORIZATION

VNS Health

Directions for Completing Compound Authorization Form For Research

The Item numbers in these directions correspond to the Section and Item numbers in the research authorization.

Section A: This Section should be completed in all instances. This Section should reflect the health information to be used in the research study and the persons or entities that will have access to the information. It may be easier for each VNS Health Covered Entity or investigator conducting the research on behalf of the VNS Health Covered Entity (who are aware of the information and uses and disclosures necessary to perform the research study) to complete this Section. Where appropriate, the appropriate information can be inserted before the subject signs the consent. For example, the information to be disclosed can be pre-printed on the form. However, the research subject should only execute the authorization when he/she is in full agreement with the information indicated.

1. Each VNS Health Covered Entity or investigator should provide a description of each purpose for which the health information will be used or/disclosed in the research study. The description should provide sufficient information to allow the research subject to make an informed decision as to whether to allow the release of the information; however, it should not be a broad or blanket statement requesting the use and/or disclosure for a wide range of unspecified purposes. If authorization is for future research, however, it is sufficient to describe that purpose such that it would be reasonable for the participant to expect his/her information could be used or disclosed for future research. This purpose description could include specific statements regarding sensitive research, if applicable.

2. Each VNS Health Covered Entity or investigator should include the name or other specific identification of the persons or classes of persons who are authorized to use and/or disclose the health information being used in the research study. If a class of persons is listed, it should be specific enough so that the reader will know, with reasonable certainty, the individuals indicated. Please note this list should be as extensive as possible and include all persons that will be necessary over the entire research study because, once completed, only the persons listed are authorized to use and/or disclose the health information in the research study.

3. Each VNS Health Covered Entity or investigator should include a description of the information to be used or disclosed in the research study. The description should be specific enough to allow the reader to know exactly what information is being referenced. For example, the description could reference “all laboratory results for Mr. X” or “all laboratory results from the months July 1999 through September 1999 for Mr. X.” Please note this description should be as extensive as possible and include all information that will be necessary over the entire research study because, once completed, only the information described can be used in the research study. Please note that there is no limit on the information that can be authorized for disclosure and, therefore, if the research participant wishes to disclose his/her entire medical record, this fact can be indicated.

4. This Item explains that the VNS Health Covered Entity is conducting research which includes treatment and is seeking to condition such treatment on the research participant executing this authorization.

5. This Item explains the VNS Health Covered Entity is seeking an authorization in connection with a clinical trial involving treatment and wishes to limit the research participant’s access to the information obtained in the course of the clinical trial.

Section B: This Section should be completed in all instances.

9. Each VNS Health Covered Entity or investigator should indicate how the research can be revoked and the specific person to which the revocation needs to be addressed. The revocation can be applied to just the conditioned or unconditioned research provided that the research participant is sufficiently explicit in his/her revocation.

10. Each VNS Health Covered Entity or investigator conducting the research on behalf of the VNS Health Covered Entity should complete the date or event upon which the authorization will expire. The expiration date or event should either be a specific date (e.g., December 20, 2003), a specific time period (e.g., one year from the date of signature) or an event directly relevant to the research participant or the purpose of the use or disclosure (e.g., for the duration of the research participant's participation in the research study). Alternatively, the statement "end of the research study," "none," or similar language is sufficient for all research, including the creation or maintenance of a research database or research repository.

Section C: This Section should be completed regarding the unconditioned research that the research participant may choose to participate in. This Section may be duplicated if more than one additional research study is being addressed.

11. Each VNS Health Covered Entity or investigator should provide a description of each purpose for which the health information will be used or/disclosed in the additional research study. The description should provide sufficient information to allow the research subject to make an informed decision as to whether to allow the release of the information; however, it should not be a broad or blanket statement requesting the use and/or disclosure for a wide range of unspecified purposes.

12. Each VNS Health Covered Entity or investigator should include the name or other specific identification of the persons or classes of persons who are authorized to use and/or disclose the health information being used in the additional research study. If a class of persons is listed, it should be specific enough so that the reader will know, with reasonable certainty, the individuals indicated. Please note this list should be as extensive as possible and include all persons that will be necessary over the entire research study because, once completed, only the persons listed are authorized to use and/or disclose the health information in the research study.

13. Each VNS Health Covered Entity or investigator should include a description of the information to be used or disclosed in the additional research study. The description should be specific enough to allow the reader to know exactly what information is being referenced. For example, the description could reference "all laboratory results for Mr. X" or "all laboratory results from the months July 1999 through September 1999 for Mr. X." Please note this description should be as extensive as possible and include all information that will be necessary over the entire research study because, once completed, only the information described can be used in the research study. Please note that there is no limit on the information that can be authorized for disclosure and, therefore, if the research participant wishes to disclose his/her entire medical record, this fact can be indicated.

14. As the research does not involve treatment, the VNS Health Covered Entity cannot condition patient treatment on execution of this authorization. The research participant should initial this Item indicating understanding that this is additional, unconditioned research in which he/she chooses to participate.

The research participant or research participant's representative should sign and date the authorization. If the authorization is completed by a research participant's representative, the

representative should also print his/her name and describe his/her authority to act on behalf of the research participant at the bottom of this Section. Lastly, the research participant or research participant's representative should be provided with a copy of the executed authorization.