Official Title: "Vestibular Rehabilitation and Otolith Dysfunction"

NCT Number: 02652442

Document date: 9-28-2021

Scientific Background: Vestibular Rehabilitation (VR) is the treatment of choice for patients experiencing dizziness, imbalance, and mobility impairments related to vestibular dysfunction. VR typically includes gaze stability exercises, which were developed to facilitate vestibular compensation of the semicircular canal-mediated vestibulo-ocular reflex (VOR). A critical signal to induce adaptation is retinal slip during head movements; thus, adaptation exercises involve head rotation while focusing on a target. Most studies examining the effectiveness of VR have used only tests of VOR function (caloric and rotational tests) that measure horizontal semicircular canal to determine vestibular loss. Thus, little is known about interventions to facilitate vestibular compensation of the otolith organs.

The concept of using centrifugation for otolith adaptation may be similar to using gaze stability exercises for VOR adaptation. Recent studies have demonstrated adaptation following otolith organ stimulation using centrifugation (or linear acceleration), but there is no data regarding optimum stimulus parameters. The purpose of this study is to determine optimal off-axis distance of the rotary chair, duration of off-axis rotation (OAR), and training schedule for otolith adaptation.

Study Objectives: The goal for testing different training protocols in healthy controls is: 1) to determine optimal stimulus parameters (off-axis distance of the rotary chair, duration of off-axis rotation, and training schedule) that will be used to treat patients with otolith dysfunction and 2) to demonstrate otolith plasticity with a given set of stimulus parameters.

Study design: Sequential assignment to stimulus parameters (off-axis distance, duration of off-axis rotation, training schedule)

Study Protocol: For healthy controls, only unilateral centrifugation (UC) training (randomized for right or left ear off-axis) will be performed. Direction (CW or CCW) of off-axis rotation (OAR) will be standardized so that subjects are facing forward in the direction of rotation.

Primary outcome measure: Static subjective visual vertical (SVV) assesses spatial perception and is influenced by otolith function. Perception of vertical is measured in a darkened room with subject seated upright. The test assesses an individual's ability to adjust a laser line to be parallel with true vertical in the absence of any other visual cues. The start position of line for SVV testing is randomized and participants are instructed to use the track ball to position the line in a vertical position. Five trials are completed, and the software calculates the distance (in degrees) from vertical. The average of the trials is calculated and used for data analysis.

Experiment 1. Determination of optimal distance of OAR (n = 5 subjects). Each subject will complete training at chair position (A) followed by (B) with at least 2 weeks in between each training session until static SVV returns to normal.

Training schedule	Chair position off-axis (cm)	Chair acceleration/ deceleration ($°/s^2$)	Chair velocity ($°/s^2$)	Duration of UC	Cycles per session	Measures
5 consecutive sessions (M-F)	(A) 3.5	5	300	90 sec accelerate to/ maintain constant velocity on-axis rotation; 1 min OAR at constant velocity; 60 sec to decelerate	5	Static SVV (5 trials) at start/end of each session
same	(B) 7.0	same	same	same	same	same

Experiment 2. Determination of duration of OAR (n = 5 subjects). Each subject will complete training at optimal chair position (determined in Exp. 1) for duration (A) followed by (B) with at least 2 weeks between each training session.

Training schedule	Chair position off-axis (cm)	Chair acceleration/ deceleration ($°/s^2$)	Chair velocity ($°/s^2$)	Duration of UC (sec)	Cycles per session	Measures
5 consecutive sessions (M-F)	Optimal distance as determined in *Exp. 1*	5	300	(A) 90 sec accelerate to/ maintain constant velocity on-axis rotation; 1 min OAR at constant velocity; 60 sec to decelerate	5	Static SVV (5 trials) at start/end of each session
same	same	same	same	(B) 90 sec accelerate to/ maintain constant velocity on-axis rotation; 3 min OAR at constant velocity; 60 sec to decelerate	same	same

Experiment 3. Determination of optimal training schedule (n = 5 subjects). Each subject will complete training at optimal chair position (determined in Exp. 1) for optimal duration (determined in Exp. 2) with intermittent schedule (B) at least 2 weeks after completion of Experiment 2.

Training schedule	Chair position off-axis (cm)	Chair acceleration/ deceleration ($°/s^2$)	Chair velocity ($°/s^2$)	Duration of UC (sec)	Cycles per session	Measures
(A) 5 consecutive sessions (M-F)	Optimal distance as	5	300	90 sec accelerate to/ maintain constant velocity on-axis rotation; optimal	5	Static SVV (5 trials) at start/end of each session

	determined in *Exp. 1*			duration of (determined in Exp. 2) OAR at constant velocity; 60 sec to decelerate		
(B) 2x/week x 3 weeks until 5 sessions completed	same	same	same	same	same	same

Statistical Analysis Plan: All data will be summarized using descriptive statistics. To examine the extent to which centrifugation parameters (distance, duration, schedule) impact the primary outcome (Subjective Visual Vertical, SVV) for healthy controls, paired t-tests will be used to examine change in static SVV (pre- to post-centrifugation). Alpha level is 0.05. No adjustments will be made for multiple comparisons.

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IRB APPROVAL – Initial Expedited Review

December 4, 2015

To : VA R&D

RE: Courtney Hall

Re: Vestibular Rehabilitation and Otolith Dysfunction
IRB#: 1215.2 s
ORSPA #:

The following items were reviewed and approved by an expedited process:

- New protocol submission, project summary, Otolith Rehab grant, dgi-fga data collection sheet, Locus of Control Scale survey, Disability Rating Scale survey, mmse survey, Health questionnaire Otolith Rehab, Vestibular Activities and Participation Measure survey, VAS scales, PASE, Geriatric Depression Scale, Geriatric Anxiety Inventory, ABC scale survey, ICD version 11/17/2015, CV for PI, HIPAA waiver

On December 3, 2015, a final approval was granted for a period not to exceed 12 months and will expire on December 2, 2016. The expedited approval of the study will be reported to the convened board on the next agenda.

The following **enclosed stamped, approved Informed Consent Documents** have been stamped with the approval and expiration date and these documents must be copied and provided to each participant prior to participant enrollment:

- Informed Consent Document (ICD 11.17.2015 stamped 12.03.2015)

Federal regulations require that a copy is given to the subject at the time of consent.

The ETSU/VA IRB has reviewed the HIPAA Authorization and determined that it is consistent with the informed consent document and protocol. Researchers are responsible for obtaining the valid, written HIPAA authorization of each individual research participant and providing a copy of the signed Authorization to each

participant. VA researchers are required to maintain the signed HIPAA Authorization in accordance with VHA's Record Control Schedule 10-1 (RCS 10-1).

This study was approved under expedited category: (4) Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.) Examples: (a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject=s privacy; (b) weighing or testing sensory acuity; (c) magnetic resonance imaging; (d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography; (e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

Projects involving VA patients, facilities or employees must also be approved by the VA Research & Development Committee prior to initiating the study.

Projects involving Mountain States Health Alliance must also be approved by MSHA following IRB approval prior to initiating the study.

Unanticipated Problems Involving Risks to Subjects or Others must be reported to the IRB (and VA R&D if applicable) within 5 working days.

Proposed changes in approved research cannot be initiated without IRB review and approval. The only exception to this rule is that a change can be made prior to IRB approval when necessary to eliminate apparent immediate hazards to the research subjects [21 CFR 56.108 (a)(4)]. In such a case, the IRB must be promptly informed of the change following its implementation (within 5 working days) on Form 109 (www.etsu.edu/irb). The IRB will review the change to determine that it is consistent with ensuring the subject's continued welfare.

Sincerely,

J Moorman, MD, PhD

Jonathan Moorman, M.D.
Vice-Chair, ETSU/VA IRB

cc: Jesse White

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IRB APPROVAL – Continuing Expedited Review

October 10, 2016

Dr. Courtney Hall

Re: Vestibular Rehabilitation and Otolith Dysfunction
IRB#: 1215.2s
ORSPA#:

The following items were reviewed and approved by an expedited process:

- xform 107, narrative portion of NPS, currently approved ICDs: Control ICD 3.11.2016 stamped approved 3.22.2016; ICD 11.17.2015 stamped 12.03.2015, abstract, VROD protocol Mar.2016, dgi-fga data collection sheet, Locus of Control Scale survey, Disability Rating Scale survey, mmse survey, Health questionnaire Otolith Rehab, Vestibular Activities and Participation Measure survey, VAS scales, PASE, Geriatric Depression Scale, Geriatric Anxiety Inventory, ABC scale survey, protocol history

On October 4, 2016, a final approval was granted for a period not to exceed 12 months and will expire on October 3, 2017. The expedited approval of the study will be reported to the convened board on the next agenda.

The following **enclosed stamped, approved ICD** has been stamped with the approval and expiration date and this document must be copied and provided to each participant prior to participant enrollment:

- Informed Consent Document **(**Control ICD 3.11.2016 stamped approved 10.4.2016; ICD 11.17.2015 stamped 10.4.2016**)**

Federal regulations require that the original copy of the participant's consent be maintained in the principal investigator's files and that a copy is given to the subject at the time of consent.

The ETSU/VA IRB has reviewed the HIPAA Authorization and determined that it is consistent with the informed consent document and protocol. Researchers are responsible for obtaining the valid,

written HIPAA authorization of each individual research participant and providing a copy of the signed Authorization to each participant. VA researchers are required to maintain the signed HIPAA Authorization in accordance with VHA's Record Control Schedule 10-1 (RCS 10-1).

This study was approved under expedited category: (7) Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(2) and (b)(3). This listing refers only to research that is not exempt.).

Unanticipated Problems Involving Risks to Subjects or Others must be reported to the IRB (and VA R&D if applicable) within 5 working days.

Proposed changes in approved research cannot be initiated without IRB review and approval. The only exception to this rule is that a change can be made prior to IRB approval when necessary to eliminate apparent immediate hazards to the research subjects [21 CFR 56.108 (a)(4)]. In such a case, the IRB must be promptly informed of the change following its implementation (within 5 working days) on Form 109 (www.etsu.edu/irb). The IRB will review the change to determine that it is consistent with ensuring the subject's continued welfare.

Sincerely,

J Moorman, MD, PhD

Dr. Jonathan Moorman, M.D., VA Vice Chair
ETSU/VA IRB

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IRB APPROVAL – Continuing Expedited Review

August 23, 2017

Dr. Courtney Hall

Re: Vestibular Rehabilitation and Otolith Dysfunction
IRB#: 1215.2s
ORSPA#:

The following items were reviewed and approved by an expedited process:

- xform 107, narrative portion of NPS, currently approved ICDs: Dizzy Participant ICD version11.17.15 stamped 10.4.2016 and Healthy Control ICD version 3.11.16 stamped 10.4.2016, abstract, VROD protocol Mar.2016, abstract, protocol history

On August 23, 2017, a final approval was granted for a period not to exceed 12 months and will expire on August 22, 2018. The expedited approval of the study will be reported to the convened board on the next agenda.

The following **enclosed stamped, approved ICD** has been stamped with the approval and expiration date and this document must be copied and provided to each participant prior to participant enrollment:

- Informed Consent Documents:
  Dizzy Participant ICD version 11.17.15 stamped 8.23.17 with HIPAA Authorization
  Healthy Control ICD version 3.11.16 stamped 8.23.17 with HIPAA Authorization

Federal regulations require that the original copy of the participant's consent be maintained in the principal investigator's files and that a copy is given to the subject at the time of consent.

The IRB Vice Chair has determined the patient's medical record must be flagged.

The ETSU/VA IRB has reviewed the HIPAA Authorization and determined that it is consistent with the informed consent document and protocol. Researchers are responsible for obtaining the valid,

written HIPAA authorization of each individual research participant and providing a copy of the signed Authorization to each participant. VA researchers are required to maintain the signed HIPAA Authorization in accordance with VHA's Record Control Schedule 10-1 (RCS 10-1).

This study was approved under expedited category: (7) Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(2) and (b)(3). This listing refers only to research that is not exempt.).

Unanticipated Problems Involving Risks to Subjects or Others must be reported to the IRB (and VA R&D if applicable) within 5 working days.

Proposed changes in approved research cannot be initiated without IRB review and approval. The only exception to this rule is that a change can be made prior to IRB approval when necessary to eliminate apparent immediate hazards to the research subjects [21 CFR 56.108 (a)(4)]. In such a case, the IRB must be promptly informed of the change following its implementation (within 5 working days) on Form 109 (www.etsu.edu/irb). The IRB will review the change to determine that it is consistent with ensuring the subject's continued welfare.

Sincerely,

J Moorman, MD, PhD

Dr. Jonathan Moorman, M.D., VA Vice Chair
ETSU/VA IRB

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IRB APPROVAL – Continuing Expedited Review

July 20, 2018

Courtney Hall, PhD

Re: Vestibular Rehabilitation and Otolith Dysfunction
IRB#: 1215.2s
ORSPA#:

The following items were reviewed and approved by an expedited process:

- xform 107, narrative portion of NPS, currently approved ICDs: Dizzy Participant ICD version 11.17.15 stamped 8.23.17 with HIPAA Authorization and Healthy Control ICD version 3.11.16 stamped 8.23.17 with HIPAA Authorization, abstract, VROD protocol Mar.2016, abstract, protocol history

On July 16, 2018, a final approval was granted for a period not to exceed 12 months and will expire on July 15, 2019. The expedited approval of the study will be reported to the convened board on the next agenda.

The following **enclosed stamped, approved ICD** has been stamped with the approval and expiration date and this document must be copied and provided to each participant prior to participant enrollment:

- Informed Consent Documents:

Dizzy Participant ICD version 11.17.15 stamped 7.16.2018 with HIPAA Authorization
Healthy Control ICD version 3.11.16 stamped 7.16.2018 with HIPAA Authorization

Federal regulations require that the original copy of the participant's consent be maintained in the principal investigator's files and that a copy is given to the subject at the time of consent.

The ETSU/VA IRB has reviewed the HIPAA Authorization and determined that it is consistent with the informed consent document and protocol. Researchers are responsible for obtaining the valid, written HIPAA authorization of each individual research participant and providing a copy of the signed

Authorization to each participant. VA researchers are required to maintain the signed HIPAA Authorization in accordance with VHA's Record Control Schedule 10-1 (RCS 10-1).

This study was approved under expedited category: (7) Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(2) and (b)(3). This listing refers only to research that is not exempt.).

Unanticipated Problems Involving Risks to Subjects or Others must be reported to the IRB (and VA R&D if applicable) within 5 working days.

Proposed changes in approved research cannot be initiated without IRB review and approval. The only exception to this rule is that a change can be made prior to IRB approval when necessary to eliminate apparent immediate hazards to the research subjects [21 CFR 56.108 (a)(4)]. In such a case, the IRB must be promptly informed of the change following its implementation (within 5 working days) on Form 109 (www.etsu.edu/irb). The IRB will review the change to determine that it is consistent with ensuring the subject's continued welfare.

Sincerely,

J Moorman, MD, PhD

Dr: Jonathan Moorman, M.D., VA Vice Chair
ETSU/VA IRB

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IRB APPROVAL – Continuing Expedited Review

May 22, 2019

Courtney Hall, PhD

Re: Vestibular Rehabilitation and Otolith Dysfunction
IRB#: 1215.2s
ORSPA#:

The following items were reviewed and approved by an expedited process:

- xform 107, narrative portion of NPS, currently approved ICDs: Dizzy Participant ICD version 11.17.15 stamped 7.16.2018 with HIPAA Authorization ; Healthy Control ICD version 3.11.16 stamped 7.16.2018 with HIPAA Authorization, abstract, VROD protocol Mar.2016, protocol history

On May 22, 2019, a final approval was granted for a period not to exceed 12 months and will expire on May 21, 2020. The expedited approval of the study will be reported to the convened board on the next agenda.

The following **enclosed stamped, approved ICD** has been stamped with the approval and expiration date and this document must be copied and provided to each participant prior to participant enrollment:

Informed Consent Documents:

- Dizzy Participant ICD version 11.17.15 stamped 5.22.2019 with HIPAA Authorization ;
- Healthy Control ICD version 3.11.16 stamped 5.22.2019 with HIPAA Authorization

Federal regulations require that the original copy of the participant's consent be maintained in the principal investigator's files and that a copy is given to the subject at the time of consent.

The ETSU/VA IRB has reviewed the HIPAA Authorization and determined that it is consistent with the informed consent document and protocol. Researchers are responsible for obtaining the valid, written HIPAA authorization of each individual research participant and providing a copy of the signed

Authorization to each participant. VA researchers are required to maintain the signed HIPAA Authorization in accordance with VHA's Record Control Schedule 10-1 (RCS 10-1).

This study was approved under expedited category: (7) Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(2) and (b)(3). This listing refers only to research that is not exempt.).

Unanticipated Problems Involving Risks to Subjects or Others must be reported to the IRB (and VA R&D if applicable) within 5 working days.

Proposed changes in approved research cannot be initiated without IRB review and approval. The only exception to this rule is that a change can be made prior to IRB approval when necessary to eliminate apparent immediate hazards to the research subjects [21 CFR 56.108 (a)(4)]. In such a case, the IRB must be promptly informed of the change following its implementation (within 5 working days) on Form 109 (www.etsu.edu/irb). The IRB will review the change to determine that it is consistent with ensuring the subject's continued welfare.

Sincerely,

J. Moorman, MD, PhD

Dr. Jonathan Moorman, M.D., VA Vice Chair
ETSU/VA IRB

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IRB APPROVAL – Continuing Expedited Review

April 2, 2020

Courtney Hall, PhD

Re: Vestibular Rehabilitation and Otolith Dysfunction
IRB#: 1215.2s
ORSPA#:

The following items were reviewed and approved by an expedited process:

- xform 107, narrative portion of NPS, currently approved Dizzy Participant ICD version 11.17.15 stamped 5.22.2019 with HIPAA Authorization ; Healthy Control ICD version 3.11.16 stamped 5.22.2019 with HIPAA Authorization, abstract, VROD protocol Mar.2016, VROD Recruitment letter v.2.1.19 stamped approved 5.22.2019, protocol history

On April 1, 2020, a final approval was granted for a period not to exceed 12 months and will expire on March 31, 2021. The expedited approval of the study will be reported to the convened board on the next agenda.

The following **enclosed stamped, approved ICD** has been stamped with the approval and expiration date and this document must be copied and provided to each participant prior to participant enrollment:

- Informed Consent Documents: **(**Dizzy Participant ICD version 11.17.15 stamped 4.1.2020 with HIPAA Authorization ; Healthy Control ICD version 3.11.16 stamped 4.1.2020 with HIPAA Authorization**)**

Federal regulations require that the original copy of the participant's consent be maintained in the principal investigator's files and that a copy is given to the subject at the time of consent.

The ETSU/VA IRB has reviewed the HIPAA Authorization and determined that it is consistent with the informed consent document and protocol. Researchers are responsible for obtaining the valid, written HIPAA authorization of each individual research participant and providing a copy of the signed

Authorization to each participant. VA researchers are required to maintain the signed HIPAA Authorization in accordance with VHA's Record Control Schedule 10-1 (RCS 10-1).

This study was approved under expedited category: (7) Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(2) and (b)(3). This listing refers only to research that is not exempt.).

Unanticipated Problems Involving Risks to Subjects or Others must be reported to the IRB (and VA R&D if applicable) within 5 working days.

Proposed changes in approved research cannot be initiated without IRB review and approval. The only exception to this rule is that a change can be made prior to IRB approval when necessary to eliminate apparent immediate hazards to the research subjects [21 CFR 56.108 (a)(4)]. In such a case, the IRB must be promptly informed of the change following its implementation (within 5 working days) on Form 109 (www.etsu.edu/irb). The IRB will review the change to determine that it is consistent with ensuring the subject's continued welfare.

Sincerely,

J Moorman, MD, PhD

Dr. Jonathan Moorman, M.D., VA Vice Chair
ETSU/VA IRB

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Continuing Review IRB Approval

May 12, 2021

Courtney Hall, PhD

Re: Vestibular Rehabilitation and Otolith Dysfunction
IRB#: 1215.2s
Sponsor: VA Funding

On May 12, 2021, IRB approval was granted for a period not to exceed 12 months and will expire on May 11, 2022. The expedited approval of the study will be reported to the convened board on the next agenda.

This study was approved under expedited category:
Category 4: Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice- excluding procedures involving x-rays or microwaves. Where medical devices are employed- they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review- including studies of cleared medical devices for new indications.) Examples: (a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject's privacy; (b) weighing or testing sensory acuity; (c) magnetic resonance imaging; (d) electrocardiography- electroencephalography- thermography- detection of natural occurring radioactivity- electroretinography- ultrasound- diagnostic infrared imaging- doppler blood flow- and echocardiography; (e) moderate exercise- muscular strength testing- body composition assessment- and flexibility testing where appropriate given the age- weight- and health of the individual.
Category 7: Research on individual or group characteristics or behavior including - but not limited to- research on perception- cognition- motivation- identity- language- communication- cultural beliefs/practices- and social behavior- or research employing survey- interview- oral history- focus group- program evaluation- human factors evaluation- or quality assurance methodologies. NOTE: some of the research in this category may be exempt [45CFR46.101(b)(2) and (b)(3). This listing refers only to research that is not exempt.
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The following items were reviewed and approved by an expedited process:

- Continuing Review, narrative portion of NPS, abstract, VROD protocol March 2016, protocol history

Note: This study is closed to accrual; therefore, there are no stamped, approved informed consent documents for the current approval period. If this study is re-opened to accrual, revised informed consent documents will have to be submitted and approved by the IRB before enrollment of participants can resume

Unanticipated Problems Involving Risks to Subjects or Others (UPIRTSOs) must be reported to the IRB and VA R&D within 5 working days.

Proposed changes in approved research cannot be initiated without IRB review and approval. The only exception is that a change can be made prior to IRB approval when necessary to eliminate apparent immediate hazards to the research subjects [45 CFR 46.108(3)(iii), 21 CFR 56.108 (a)(4)]. In such a case, the IRB must be promptly informed of the change following its implementation (within 5 working days) on xForm 109. The IRB will review the change to determine that it is consistent with ensuring the subjects' continued welfare.

Sincerely,

Jon Moorman, M.D., Ph.D.
VA Vice Chair, ETSU/VA IRB