***VA Sierra Nevada Health Care System (VASNHCS)***

***RESEARCH PROTOCOL GUIDANCE AND TEMPLATE***

***INSTRUCTIONS AND GUIDANCE: When composing a new local protocol, delete all instructions in italics or blue font, including those in red, so that no instructions are contained in the final version of your document. All required sections and text are in black font.***

***IRB EXEMPT RESEARCH:*** *In contrast to research studies that require a full IRB review*, some studies may qualify for IRB exemption if certain criteria are met. Please refer to the Research Form 130 you will submit along with this protocol to evaluate if your study qualifies for IRB exemption.

*Note: Any IRB exempt research study will require a waiver of HIPAA authorization to access protected health information (PHI). Written consent may also be required depending on the type of exempt research being conducted (see consent section of template).*

***SINGLE SITE STUDY:*** *If the research will be conducted only at the VASNHCS and there are no other participating sites, submit a protocol that provides details for each of the required protocol elements in the “Required Protocol Elements” section of this document.*

***RECRUITMENT STUDY:***  *The VASNHCS Research & Development Committee (RDC) can only approve research that supports VHA’s mission to advance the health care of our nation’s Veterans. To recruit patients from the VASNHCS for a non-VA study (e.g., a study approved by and conducted at UNR), the VA protocol must have strong rationale for Veteran participation and describe the relevance of the research and how the research would benefit the Veteran population. Both the protocol and informed consent form should focus on procedures being conducted at the VASNHCS (e.g., screening and/or recruiting). The procedures occurring at the other site may be briefly summarized but with a clear indication that the VHA is not responsible for the conduct of that portion or phase of the study.*

*Include the protocol from the other site for informational purposes; the VASNHCS RDC will not critique or approve the other site’s protocol but will consider the relevance and risks to veterans before approving recruitment from the VASNHCS .*

*Plans for protecting privacy and information security are crucial. Be specific about what information will be provided to the non-VA site and how data will be transferred. Also indicate if the VA PI will participate in data analysis or manuscript preparation.*

*NOTE: This guidance does not preclude VASNHCS clinicians, in the normal course of their clinical duties, from discussing specific research studies with their patients where appropriate and referring them to a non-VA investigator for more information about a non-VA study. However, VASNHCS personnel should not provide the non-VA investigator with the names or contact information of Veterans who might be eligible for the study. Instead, the VASNHCS clinician should provide the Veteran with the contact information for the non-VA investigator so the Veteran may initiate contact if he/she is interested in participating in the non-VA study. VASNHCS personnel should not provide the non-VA investigator with protected health information (PHI) about Veterans who choose to participate in non-VA studies without a signed release form,* ***and*** *a signed HIPAA authorization,* ***and*** *adherence to local requirements for the release of medical information.*

***MULTI-SITE STUDY:*** *If the research will be conducted at the VASNHCS but VASNHCS is one of many sites, there should one “original” or “parent” protocol, usually created by the study sponsor or lead investigator. This must be submitted for IRB review. In addition, there should also be a brief VASNHCS -specific protocol (“local protocol) that adequately addresses:*

* *Any aspect(s) of the original/parent protocol that will not be conducted at the VASNHCS .*
* *Any alteration(s) of procedure(s) in the original/parent protocol and how the alteration affects the local risk/benefit ratio.*
* *Role of individual(s) (i.e., Co-Investigator or usual-care clinician) performing procedure(s) involving clinical care. Describe any special training required as appropriate for non-clinicians.*
* *Handling of adverse events, data storage, information security, and privacy/confidentiality issues.*
* *Procedures for identifying, recruiting, enrolling, and following participants (as appropriate) at the VASNHCS .*
* *Any other issues specific to the VASNHCS that are not stated in the original protocol, such as process of participant compensation or information regarding usual care.*

*These items should be addressed in addition to the required elements described in the “Required Protocol Elements” section of this document.*

*In the local protocol, for ALL the required elements:*

* *Specify the page(s) of the original/parent protocol on which this information is located, and*
* *State that the local protocol does not differ from the original/parent protocol regarding this element—****OR—****note**any exceptions.*

***COLLABORATIVE RESEARCH:***

*Protocols for “collaborative” research studies must clearly separate VA research activities and VA data from non-VA research activities and non-VA data. Investigators with dual appointments at a VA facility and a non-VA (affiliate) institution must separate and document their activities as VA employees on VA time versus their activities as affiliate/collaborator employees on affiliate/collaborator time. The protocol must clarify (i) VA duties, (ii) VA duty locations, (iii) VA tours of duty or time allocations, (iv) issues related to data ownership, and (v) research information protection and data security requirements. The VASNHCS -specific protocol must:*

* *Describe all data collection activities for the VA research to be included in the “collaborative” study (including location of collection and storage, access and use, statistical analyses, and security measures)\*
* *If VA data will be combined with non-VA data, describe when and how this will occur and where the combined data will be stored*
* *Identify any VA research activities occurring at non-VA sites (i.e., at non-VA properties).*
* *Provide a copy of any memorandum of understanding (MOU) with the non-VA entity describing data ownership or data security arrangements for the “collaborative” study.*
* *If the protocol involves data collected in non-VA research (i.e., not collected by VA investigators serving on compensated, WOC, or IPA appointments while on VA time, utilizing VA resources, or on VA property including space leased to, or used by VA), explain how non-VA activities and data are separated from VA activities and data.*

***VASNHCS REQUIRED ELEMENTS AND PROTOCOL TEMPLATE***

***General Information***

* *The protocol should have the following items clearly accessible, either on a cover page or as running headers or footers:*
* *Protocol Title*
* *Name of Principal Investigator/Local Site Investigator*
* *Protocol Version and Date*
* *All protocol pages must be numbered.*
* *The protocol should indicate if the local PI a clinician or non-clinician.*
* *If the PI is a non-clinician and medical procedures are being performed, the protocol must have provisions for enlisting the services of a clinician with appropriate expertise and privileges to perform duties that may include: medical procedures, reviewing data for safety concerns, reviewing adverse events and new study findings, and making required decisions to protect the health of the participant. If not applicable, state why.*

***Note:*** *If applicable, please ensure that the protocol, informed consent form, and HIPAA authorization are congruent—the information in all three documents must be consistent with each other.*

**PROTOCOL TITLE:** *(Include the full protocol title)*

**PROTOCOL NUMBER***: (to be assigned upon submission)*

**SHORT TITLE:** *(Include a short title that will be used to refer to this protocol)*

**PRINCIPAL INVESTIGATOR:** *(**VASNHCS PI)*

**CO-INVESTIGATOR(S):** *(remove if not applicable)*

**VERSION NUMBER AND DATE:** *(Include the version number and version date; this information may be included in a header or footer. In addition, complete the table below with subsequent versions)*

|  |  |
| --- | --- |
| ***Version number*** | ***Summary of changes*** |
| *1* | *n/a - original submission* |
|  |  |
|  |  |
|  |  |
|  |  |
|  |  |

**SPONSOR/FUNDING SOURCE*:*** *(state unfunded or N/A if not applicable)*

**eIRB:** (remove if not applicable)

**IND Number(s) / IDE Number(s):** (remove if not applicable)

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***Note:*** *To update the table of contents click on the table and select “update table of contents” in the upper left corner of the table. You will need to update the table once you have completed the protocol to ensure your page numbers align correctly with your headings.*

# 1 ABBREVIATIONS

*Use this section to list any abbreviations you plan to use in your protocol. For example:*

*FBD Functional Bowel Disorder*

*IBS-D Diarrhea prominent irritable bowel syndrome*

*For other common abbreviations check out:* [*https://www.rochester.edu/ohsp/documents/rsrb/pdf/Acronyms.pdf*](https://www.rochester.edu/ohsp/documents/rsrb/pdf/Acronyms.pdf)

# 2 STUDY OBJECTIVES (OR AIMS)

*Provide a general description of purpose of the study.* *The study objectives (or aims) should be broken down into primary and secondary objectives. The objectives need to be specific to the intervention - for a drug, they should specify the dosage level, route, frequency and duration of administration and in a defined population - "does the study drug reduce blood pressure when administered twice a day as an oral liquid, at a dose of 50 mg, in children age 6 - 12 years who have moderate hypertension". The objectives are usually written as bullet points.*

*The primary objective is to determine (or evaluate) the... (efficacy, pharmacokinetics, safety, etc.)... of the study intervention...*

*The primary objective serves as the basis of the sample size. Secondary objectives may be exploratory or hypothesis generating, and the study may not be powered to achieve these objectives.*

*Each objective has a corresponding endpoint and a corresponding analysis plan. The endpoints in the IRB's protocol templates are located in the analysis section. Some protocols include a table that maps each objective to its endpoint and corresponding analysis plan.*

# 3 BACKGROUND AND SIGNIFICANCE

*Include a discussion of important literature or data that are relevant to the study and that provide background for the study; provide applicable clinical, epidemiological or public health background or context of the study; state the importance of the study to the VA’s mission and any relevant treatment issues or controversies, etc.*

# 4 DESIGN

*Describe of the type/design of study to be conducted (e.g., placebo-controlled, double-mask, parallel design, open-label, dose escalation, instrument validation, focus group, etc.). Include variables, measures, objectives, endpoints, or outcomes, as applicable. Ideally include a study design/flow diagram*

# 5 RISK/BENEFIT ASSESSMENT

*Describe how risks and discomforts will be minimized. Consider physical, psychological, legal, economic, social, and genetic risks.*

# 6 SELECTION OF PARTICIPANTS

*The protocol should have a clear set of inclusion and exclusion criteria (bulleted or numbered lists are preferred). Indicate how potential participants will be identified. Indicate the number of participants that will be enrolled over all sites (if applicable) and how many participants will be enrolled at VASNHCS. It may be helpful to state that you will screen/consent individuals until you meet the desired sample size of X participants. Describe safeguards for vulnerable populations or those participants who may be susceptible to coercion or undue influence.*

# 7 PARTICPANT RECRUITMENT

*Provide a plan for just, fair, and equitable recruitment and selection of participants. All studies (prospective, retrospective, data/sample repositories, etc.) must describe participant recruitment. If participants are contacted about the study, include specifics of how this contact will be made. This is typically not well described in original/parent protocols for multi-site studies but is necessary for IRB approval. For prospective studies involving interaction or intervention with participants, include one or both statements, as applicable:* For the purposes of screening, recruiting, and determining eligibility information will be obtained through written communication with the prospective participant [*or* legally authorized representative] *and/or* identifiable private information [*or* identifiable biospecimens] will be obtained by accessing medical records [*or* stored identifiable biospecimens].

# 8 CONSENT PROCESS

*Describe the consent process. Indicate whether the study will utilize a waiver of informed consent or a waiver of documented informed consent (e.g., verbal consent but no signed consent document).*

***Note:*** *If your study is determined to meet the criteria for IRB exemption as outlined in VHA Directive 1200.05(2), you may still be required to obtain written informed consent if the study involves the investigator interacting with human participants or obtaining information by educational tests, surveys, interview procedures, or behavioral interventions. If your research study receives an IRB exemption and will utilize any of the methods outlined above, the study team must provide the following information to the participant in writing:*

*(1) The activity is research.*

*(2) Participation is voluntary.*

*(3) Permission to participate can be withdrawn.*

*(4) Permission for use of data can be withdrawn for exempt research activities involving the collection and use of identifiable data; and*

*(5) Contact information for the VA Investigator.*

# 9 HEALTH INSURANCE PORTABILITY AND ACCOUNTABILITY ACT (HIPAA)

* This study will require participants to sign a HIPAA authorization that outlines how PHII will be used, shared, and stored.
* This study will access PHI without a signed HIPAA authorization and will request a waiver of HIPAA authorization from the IRB (or the local privacy board if the study is determined to be exempt research).

*If the study will require a HIPAA waiver to access PHI at any point in the study, please describe when, how, and who will access this information and/or If the study will require the research team to obtain written HIPAA authorization, describe when, how, and who will be responsible from obtaining it.*

# 10 STUDY INTERVENTIONS, MEASUREMENTS AND EVALUATIONS

*Describe study related treatment (the use of a table of procedures/evaluations may be helpful). If the protocol involves “usual care,” the protocol must clearly differentiate the research intervention(s) from “usual care” (whether the “usual care” is limited to one “arm” of the study or is being delivered to all study participants). Also, the protocol must clearly designate the individual or entity (e.g., the appropriate research personnel versus the participant’s health care provider) responsible for relevant aspects of both the research and the usual care.*

*The Study Measurements should provide the detailed descriptions for how each measurement will be made including. For example, if blood pressure will be measured, it is important to state the subject"s condition (resting for at least 5 minutes), position (seated), arm (left) and technique (mercury sphygmomanometer)..*

*Psychological or other measurement scales that will be used should be described. Those that have been validated and that are on the IRB's listing of Validated Instruments may simply be referenced. Those that are not on the list should be included in the appendix or uploaded into eIRB.*

*It is not necessary to include a copy of the case report form if all of the study measurements are listed in this section of the protocol. The protocol template also includes an alternative table format that may be easier for certain measurements such as laboratory tests.*

*The section on unscheduled visits may be applicable when patients are anticipated to require rescue therapy or might need interim care due to chronic illness.*

*For studies involving biospecimens: Describe if whole genome sequencing (i.e., sequencing of human germline or somatic specimen with intent to generate the genome or exome sequence of that specimen) will occur. Also include whether specimens will be labeled with identifiable, coded, or de-identified information.*

*For clinical studies, recommend inclusion of a schedule of events or table of procedures. Example can be found here:* [*https://irb.research.chop.edu/writing-protocol*](https://irb.research.chop.edu/writing-protocol)

***Note:*** *To decrease the number of protocol deviations, describe and, if applicable, provide a plan to manage any foreseeable issues regarding study conduct (e.g., expected lost equipment or expected missed or out of window visits).*

# 11 ADVERSE EVENTS

*Given the study population, disease/illness/condition state being studied, and drug information (as applicable); describe common foreseeable adverse events (i.e., the “expected” or “anticipated” adverse events or serious adverse events). The protocol should state:* *[Required]* All adverse events will be reported per VASNHCS requirements. All Serious, Unanticipated and Related adverse events will be reported to IRB within 5 business days of hearing of the event. All other adverse events will be reported at continuing review.

# 12 COST AND/OR PAYMENTS TO PARTICPANTS

*If applicable, add any research-related costs to participants. Describe what payments or other compensations are provided, how they will be made, and what situations may result in partial payment.*

# 13 DATA AND SAFETY MONITORING

*Future Data Use: If the data may be reused in other studies, the protocol must:*

1. *Describe the research data repository in which the data is to be stored, or, if data repository created through another IRB-approved protocol, identify by title and PI, and then briefly summarize relevant points from that protocol.*
2. *Provide for informed consent and a HIPAA authorization that includes language on the uses and disclosures of the data as defined in the protocol as well as information on how privacy and confidentiality will be maintained and how the data will be secured,* ***OR*** *request a waiver or alteration of informed consent and HIPAA authorization. The waiver request must address how the future data use will not affect the rights or privacy of the participants.*

*Prospective Studies: Describe the data and safety monitoring plan for prospective studies. (Some studies may not have appreciable safety risks.) This plan must include, but is not limited to, the following:*

1. *What safety information will be collected including SAEs*
2. *How the safety information will be collected (e.g., with case report forms, at study visits, by telephone calls with participants);*
3. *The frequency of data collection including when safety data collection starts;*
4. *The frequency or periodicity of review of cumulative safety data;*
5. *If not using a Data Management Committee (DMC), and if applicable, statistical tests for analyzing the safety data to determine if harm is occurring;*
6. *Provisions for the oversight of safety data (e.g., by a DMC); and*
7. *Conditions that trigger an immediate suspension of the research, if applicable.*

***NOTE:*** *The data and safety monitoring plan may vary depending on the potential risks, complexity, and nature of the study. The use of an independent DMC needs to be considered if there are multiple clinical sites, the study is blinded, interventions are high-risk, vulnerable populations are included, or when required by the funding organization, FDA, sponsor, or other relevant entity.*

*Retrospective Studies: Describe the safety and monitoring plan for retrospective studies, including studies involving pre-existing data and biological specimens. When applicable, the plan needs to include, but is not limited to, the following:*

1. *A discussion with the participant of potential study outcomes that may have an effect on the participant’s health or well-being; and*
2. *A procedure to determine when and how to notify individual participants or their health care providers of findings that may affect the participants’ health.*

# 14 WITHDRAWL OF PARTICPANTS

*Describe any anticipated circumstances under which participants will be withdrawn from the research without their consent.*

*Describe the consequences of a participant's decision to withdraw from the research and the procedures for orderly termination of participation by the participant (e.g., the participant contacting the investigator for an end-of-study visit).*

# 15 DATA ANALYSIS AND STATISTICAL CONSIDERATIONS

*Study Endpoints or Outcomes translate the study objectives into explicit statements that describe the comparisons to be made.*

*For each endpoint or outcome, the trial protocol should define four components:*

1. *the specific measurement variable, which corresponds to the data collected directly from trial participants (eg, Beck Depression Inventory score, all cause mortality);*
2. *the participant-level analysis metric, which corresponds to the format of the outcome data that will be used from each trial participant for analysis (eg, change from baseline, final value, time to event);*
3. *the method of aggregation, which refers to the summary measure format for each study group (eg, mean, proportion with score > 2); and*
4. *the specific measurement time point of interest for analysis.*

*If the objective is to determine the efficacy of Drug A compared to placebo for the treatment of hypertension, the study endpoint might be the change in the mean (method of aggregation) systolic blood pressure (measurement variable) for Drug A compared to placebo between Visit 1 and Visit 4 (participant analysis metric and time point of interest).*

*Sample Size and Power: All studies require a justification for the chosen sample size. Often the sample size is based on a formal power calculation. When this is the case, the planned sample size should be large enough to have a high probability (power) of detecting a true effect of a given magnitude, should it exist. When a power calculation is performed the protocol should include the following:*

* *the primary endpoint (outcome);*
* *the values assumed for the outcome in each study group (eg, proportion with event, or mean and standard deviation);*
* *the planned statistical test;*
* *alpha (type 1 error) level;*
* *power (usually at least 80%); and*
* *the calculated sample size per group - both assuming no loss of data and, if relevant, after any inflation for anticipated missing data modified from SPIRIT 2012 explanation and elaboration: guidance for protocols of clinical trials(link is external)*

***Note:*** *Some studies, such as exploratory studies, studies of rare diseases or pharmacokinetic trials may have a sample size that is based on more pragmatic criteria rather than a power analysis.*

*Regardless of whether or not there is a formal power calculation, the Sample Size section should provide sufficient information to explain the why the study is proposing to enroll the specified number of subjects and not more or fewer. The number of subjects needs to be sufficient to enable the study to achieve its objectives without being any larger than necessary. The IRB is required to ensure that the proposed study is feasible and minimizes risk. A study that is not large enough to achieve the stated objectives is not considered scientifically valid. A study that is larger than necessary exposes more subjects to risk and inconvenience than required to achieve the scientific aims.*

*Analysis Plan provides the specific plan for how each component of the analysis will be performed. It is insufficient to merely list the tests to be used without including a discussion of exactly what comparisons will be performed. The Analysis Plan provides a justification for the data that will be collected. The IRB will not approve collection of extraneous data without a plan for how it will be used.*

*Inadequate analytic plans are the most frequent shortcoming of investigator-initiated research. Statistical consultation should be sought prior to submission of the protocol not after completion of the study. Descriptive studies are limited to summaries of the data (means, medians, standard deviations, etc.) and do not require a very detailed plan. The analysis of observational research study designs is usually more complex than for clinical trials. A plan is needed to deal with all the sources of bias and for confounding variables.*

# 16 PRIVACY, CONFIDENTIALITY, AND INFORMATION SECURITY

**Instructions:** The template below should be included in the body of the IRB protocol. The Privacy, Confidentiality, and Information Security Section below does not replace the Privacy Officer (PO)/ Enterprise Research Data Security Plan (ERDSP) Checklist or other required submission documents. Portions below that are not applicable to your study should be left blank (you may indicate “N/A” if you wish). Blue instructional text should be deleted once you have addressed the content in each section. If you are sharing data with several sources please consider including a table that contains information such as the data recipient and the level of data (e.g., de-identified, coded, identifiable, or identified) being shared. Please contact the POs/Information Security System Officer(ISSO) if you have questions regarding completion of the Privacy, Confidentiality, and Information Security section of the IRB protocol.

1. **Lists of Data Reviewed and/or Collected for Screening/Recruitment and Conduction of Study:**

***Note:*** *data listed below must be consistent with data indicated on HIPAA waivers and/or authorizations and the ICF/ICF waiver. If using established surveys, provide the name of the survey.* *If applicable, refer to items in appendices (e.g., eCRF, surveys in appendix, etc.). If you plan to collect full or partial social security numbers, please provide a detailed justification as to why the research could not be completed without this information.*

The Personal Health Information that will be obtained, used, and/or shared for this study includes: <Check all that apply>

| **Identifier(s)** | **Source(s) of Health Information** |
| --- | --- |
| [ ]  Names | [ ]  Medical history & physical exam information |
| [ ]  All geographic subdivisions smaller than a State, including street address, city, county, precinct, and zip code. Describe: | [ ]  Photographs, videotapes, audiotapes, or digital or other images |
| [ ]  All elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, visit or treatment dates, etc.; and all ages over 89, Describe: | [ ]  Biologic specimens (e.g., blood, tissue, urine, saliva). Describe: |
| [ ]  Telephone numbers | [ ]  Progress notes |
| [ ]  Fax numbers | [ ]  Diagnostic / Laboratory test results |
| [ ]  Electronic mail addresses | [ ]  Operative reports |
| [ ]  Social Security Numbers  | [ ]  Imaging (x-ray, CT, MRI, etc.) |
| [ ]  Medical record numbers | [ ]  Discharge summaries |
| [ ]  Health plan beneficiary numbers | [ ]  Survey / Questionnaire responses |
| [ ]  Account numbers | [ ]  Billing records |
| [ ]  Certificate and/or license numbers  | [ ]  HIV testing or infection records |
| [ ]  Vehicle identifiers and serial numbers, including license plate numbers  | [ ]  Sickle cell anemia information |
| [ ]  Device identifiers and serial numbers | [ ]  Alcoholism or alcohol use information |
| [ ]  Web Universal Resource Locators (URLs) | [ ]  Drug abuse information |
| [ ]  Internet Protocol (IP) address numbers | [ ]  Mental health (not psychotherapy) notes |
| [ ]  Biometric identifiers, including finger & voice prints | [ ]  Psychological test results |
| [ ]  Full-face photographic images and any comparable images | [ ]  Genetic testing |
| [ ]  Any other unique identifying number, characteristic, or code, describe :       *\*Note: This is not the unique code assigned to otherwise de-identified health information for re-identification purposes.* | [ ]  Other, describe:       |

<retain the following statement if non-Veterans (this includes employees) will be enrolled in this study>: All non-Veterans enrolled in this study will receive the VA Notice of Privacy Practices (NOPP) and are requested to sign the acknowledgment form. The signed acknowledgment form will be maintained with the research records.

1. **Data and/or Specimen Acquisition:**

Data for this study will be collected through (*check all that apply*):

[ ]  Prospective data and/or specimen collection obtained from participants. Provide description of processes:      .

[ ]  Retrospective data collection and/or specimens obtained from medical chart review/data access. Describe how data will be obtained (e.g., fileman, CDW, etc.):      .

[ ]  Retrospective data collection and/or specimens obtained from an IRB-approved data and/or specimen repository. Indicate the repository source including name, VA location, and IRB number:      .

*Note: for data and/or specimens obtained from a VA approved data repository, a Data Use Agreement (DUA) must be executed prior to obtaining data and/or specimens. See VHA Handbook 1200.12 for further information.*

1. **Level of Data:**

The following level(s) of data will be acquired/maintained for this study (*check all that apply*):

[ ]  Identifiable—Data contains direct identifiers.

[ ]  Coded—Data linked to a specific by a code rather than a direct identifier for re-identification purposes. Only someone possessing the key to the code can link the data to a particular participant.

[ ]  De-Identified (all 18 HIPAA identifiers removed)

[ ]  Verified Statistically

 OR

[ ]  Verified by Absence or Removal of 18 HIPAA identifiers

[ ]  Limited Data Set

[ ]  Other: Describe:

1. **Location of Data and/or Specimens, and Data Retention Plan:**

A. Data and/or Specimen Location: <Please indicate the data storage plan/location for all data collected during screening/recruitment and all data collected during conduct of the study, as applicable. In addition, indicate location of specimen storage, how specimens are labeled, and what happens to unused specimens, if applicable>.

Data will be stored electronically in <insert full file path name or location here, e.g., *\\r01renhsm01.r01.med.va.gov\research\Principal Investigators*>. Data that will be stored electronically include <insert summary description of electronic data/records; you may refer the reader to other sections if there is a summary elsewhere>.

Paper records of data include <insert summary description of paper data/records> and will be stored <insert building name and room number>.

Specimens include <insert description of specimens> and will be stored <insert building name and room number>.

**[ ]** Data will be also be placed at the VA Informatics and Computing Interface (VINCI; <http://vaww.vinci.med.va.gov/vincicentral/VINCIWorkspace.aspx>). The VA Informatics and Computing Infrastructure is a partnership between the VA Office of Information Technology and the Veterans’ Health Administration Office of Research and Development. Researchers and operations staff can use VINCI to access data and statistical analysis tools in a virtual working environment through a certified VHA network computer using the VA Intranet or Virtual Private Network (VPN).

B. Data Retention Plan

[ ]  Research records will be maintained and destroyed according to VHA Records Control Schedule (RCS) 10-1. Records destruction, when authorized, will be accomplished using the then current requirements for the secure disposal of paper and electronic records as outlined in RCS 10-1. Records will not be destroyed without pre-notification to the facility records manager.

[ ]  Other data retention plan, describe:

1. **Data Access and Data Recipients:** <Insert list of entities (if relevant individuals) who will have access to the data, in what level (e.g., identified, coded, de-identified), in what location (e.g., behind the VA firewall, at VINCI, etc.), and for what purpose (e.g., analysis of data). Include entities/recipients, whether inside or outside VHA to whom data will be disclosed and/or shared (e.g., other VA hospitals, on-site monitors from sponsor, etc.)>.

*For example, “Only members of our VASNHCS research team will have access to identifiers and coded data. Coded data with direct identifiers removed (i.e., name, address, telephone numbers, SSN, DOB) will be placed at VINCI. Research collaborations from the Boston and the San Diego VAs will be given access to the coded data on the VINCI site for the purpose of data analysis. This same coded data will be shared with Dr. Jane Doe at Duke University as she will be providing expertise in genetic analysis that is not available to our team within VA.”*

< required content please retain, may edit language if all elements are still included> All VA research personnel who have access to VHA records are instructed, in accordance with VA policy, on the requirements of Federal privacy and information laws and regulations, VA regulations and policies, and VHA policy. All study personnel who are VA employees working within the VA system have fulfilled all required HIPAA and other VA security and privacy policy training requirements and have agreed to follow guidelines pertaining to the protection of patient data. All study staff are up to date with VA Privacy and Information Security Awareness and Rules of Behavior , and Privacy and HIPAA training. The data security and privacy procedures summarized in that course include logging off or locking the computer when walking away from it; no sharing of access codes, verify codes or passwords; not allowing anyone else to use the computer under one’s password; and disposing of sensitive information using VA-approved methods (e.g., shredder bins).

< required content please retain, may edit language if all elements are still included > Access to study data will be removed for all study personnel when they are no longer part of the research team.

1. **Data and/or Specimen Transportation and/or Transmission for all data and/or specimens involved in the study:**

<Insert brief description of transportation or transmission of data (if applicable) then check all that apply below>.

1. [ ]  Data and/or specimens will not be transported or transmitted outside of VASNHCS environment.
2. [ ]  Data and/or specimens will be transported BETWEEN sites that are under the auspices of the VASNHCS VA Medical Center. <insert brief description of transportation of data and/or specimens between sites and rationale for doing so. For example, if you will conduct your study at the Carson Valley CBOC and then transport paper study materials back to VASNHCS main campus, this transporting of VA sensitive information needs to be captured here as the data and/or specimens temporarily leave the protected VA environment. Please describe what is being transported, who will be responsible for transporting (study titles rather than names) how it will be secured during transport, and whether additional stops will be made while transporting the data/specimens. >
3. [ ]  Data and/or specimens will be transmitted to other VA sites using the following method(s):
4. **Data**

[ ]  Data are de-identified and thus will be sent via unencrypted e-mail or unencrypted disk (encryption is optional).

[ ]  Data are coded or contain identifiers and thus will be sent <choose method of transfer such as: PKI or RMS encrypted e-mail, FIPS 140-2 encrypted disk (with VA-authorized carrier and tracking), or FIPS 140-2 encrypted external drive (with VA-authorized carrier and tracking). You may identify a primary and secondary method>.

[ ]  Other, describe:

1. **Specimens**

[ ]  Specimens are de-identified and thus will be sent via standard carrier (tracking is optional).

[ ]  Specimens are coded or contain identifiers and thus will be sent via VA-authorized carrier with tracking.

[ ]  Other, describe:

1. [ ]  Data and/or specimens will be transported to non-VA/VHA sites (e.g., academic affiliates, laboratories, etc.) using the following method(s):
2. **Data**

[ ]  Data are de-identified and thus will be sent via unencrypted e-mail or unencrypted CD.

[ ]  Data are coded orcontain identifiers and thus will be sent via <choose method of transfer such as FIPS 140-2 encrypted CD or FIPS 140-2 encrypted hard drive/flash drive> using VA—approved carrier with tracking.

[ ]  Data are coded or identified and will be sent via the Safe Access File Exchange (SAFE) at <https://safe.amrdec.army.mil/safe/>. SAFE is a secure method of exchanging files <2GB to and from individuals with a valid .gov, .mil, .com, or .edu email address. <insert information including collaborator name.>

[ ]  Data are coded or identified and will be uploaded to sponsor website using electronic case report form (eCRF) <insert information including sponsor name and URL and the encryption the site uses.>

[ ]  Data will be collected through mobile devices ***Note:*** *All mobile/portable devices and media and any information transmitted to and from a wireless device must be protected with VA approved encryption technology that is FIPS 140-2 validated. Original electronic VA research data stored on a mobile device or outside the VA protected environment will be backed up regularly and stored securely within VA’s protected environment*.<insert information that includes the encryption technology used for these devices and how the study will ensure devices are backed up regularly and information stored within the VA protected environment>

[ ]  Other, describe:

1. **Specimens**

[ ]  Specimens are de-identified and thus will be sent via standard carrier (tracking is optional) or will be hand-delivered by research study personnel. Specify method of delivery:

[ ]  Specimens are coded and thus will be sent via VA-approved carrier with tracking or will be hand-delivered by research study personnel. Specify method of delivery:

< required content please retain, may edit language if all elements are still included> In accordance with the HIPAA and the Privacy Act, for any coded or identifiable data or specimens released from the VASNHCS (with the exception of Limited Data Sets), an Accounting of Disclosure (AOD) will be maintained (e.g., in a database or spreadsheet) that includes the participant’s name, date of the disclosure, description of the nature of the Individually Identifiable Information (III) disclosed, purpose of each disclosure, and the name and address of the person/agency to whom the disclosure was made.

***Note:*** If you intend to send specimens outside of the VASNHCS to another entity such as a reference lab or university you will need to establish a material transfer agreement (MTA). However, if your study is funded, you specimen transfers will be covered in the Cooperative Research and Development Agreement (CRADA) and an MTA is not required. Please contact the research office at V21RENResearch@va.gov to determine if you will need an MTA or CRADA.

**C.** [ ]  Local VASNHCS memorandum “Authorization to Use, Process, Store, or Transmit VA Sensitive Information Outside VA Owned or Managed Facilities” has been pre-filled out for each study team member who may transport the data and/or specimens off-site. This (these) forms are included with the IRB materials. <Please contact the facility privacy or security officer to obtain a copy of the form.>

***Note****: The memo referenced above is required to be fully signed for each study team member BEFORE any data can be transported by that individual.*

**D.** [ ]  Containers (e.g., briefcase, bin) are labeled with the following notice (label placed on the outside of container) in accordance with VHA Directive 6609:

NOTICE!!!

Access to these records is limited to: AUTHORIZED PERSONS ONLY.

Information may not be disclosed from this file unless permitted by all applicable legal authorities, which may include the Privacy Act; 38 U.S.C. §§ 5701, 5705, 7332; the Health Insurance Portability and Accountability Act; and regulations implementing those provisions, at 38 C.F.R. §§ 1.460 – 1.599 and 45 C.F.R. Parts 160 and 164. Anyone who discloses information in violation of the above provisions may subject to civil and criminal penalties.

1. [ ]  We will communicate with veterans enrolled as participants in this research study through MyHealtheVet.
2. **Risk Mitigation Strategies:**

<In addition to checking any relevant boxes below, include below a description of strategies that will be used to reduce the risk of a privacy or security incident such as theft or loss of data, unauthorized access of sensitive data or non-compliance with security controls. In addition to the PI, list other individuals (if any) who bear responsibility for overseeing the privacy and security of the data such as study coordinator, statistician, etc.

[ ]  Data are fully de-identified (sanitized of HIPAA 18 and study ID/code) before being shared outside of VASNHCS .

[ ]  Specimens are fully de-identified (sanitized of HIPAA 18 and study ID/code before being shared outside of VASNHCS .

[ ]  Data or specimens are coded, and the code is not related to, or derived from, information about the individual and that code is not otherwise capable of being translated as to the identify the individual. Only someone possessing the key to code can link the data to a particular participant.

[ ]  Other, specify:

1. **Suspected Loss of VA Information:**

Should any incident such as theft or loss of data, unauthorized access of sensitive data or non-compliance with security controls occur it will be immediately reported to the PO, ISSO, and applicable regulatory bodies as outlined in the VA’s policies and procedures for incident reporting. Both the ISSO and PO will be notified within 1 hour of acknowledgement of the issue or incident. **Reporting of Results:**

**[ ]** Reporting of results, such as in scientific papers and presentations, will never identify individual participants. Data will be presented in aggregate and individual-level data will not be published.

[ ]  Other results reporting plan, describe:

1. **Future Use of Data:**

**[ ]** Data will be retained for future use. This is described elsewhere in the protocol and is noted in the HIPAA authorization.

 **[ ]** Future Use of data is optional (i.e., not required by the research participant).

[ ]  Future Use of data is required for participation in the study.

[ ]  No future use of data is currently planned.

1. Use of Mail Merge Technology

[ ]  Mail merge programs will be used to generate letters and/or address labels for mailings to potential or already enrolled research participants. The study team is aware that to reduce risk of mail merge related privacy incidents, use of mail merge programs requires a 25% accuracy check to verify that (potential) research participant name and mailing address are properly “matched”. If discrepancies are found, a 100% accuracy check is required before letters may be mailed.

1. Use of Non-Standard Software

[ ]  I do NOT intend to use any new specialized software (i.e. Software that’s not already approved OR installed) in this study.

[ ]  I intend to use specialized software that has not already been installed and it has been approved for use by the VA Technical Reference Model (TRM) Group.

(Note: All new software must be approved by TRM before it can be installed on VA systems.)

[ ]  I intend to use previously installed software on my VA computer.

<Provide the name of the software and a description of how it will be used.>

1. Use of Cloud Computing Services

[ ]  Cloud computing services will NOT be used in this study.

[ ]  Cloud computing services WILL be used in this study as described below and have been approved nationally by the VA Chief Information Officer (CIO). (Note: ONLY cloud computing services that have been approved nationally may be used.)

<Provide the name of the cloud computing service and a description of how it will be used.>

# 17 SAFETY MANAGEMENT

Greater than Minimal Risk Safety Management:

A generic safety plan for greater than minimal risk research is included in the protocol templates. The plan includes the definitions of an adverse event, serious adverse event and summarizes the reporting requirements and timelines. A thorough discussion of reporting requirements for unanticipated problems involving risks to subjects and others, including Serious Adverse Events is available on the IRB webpage on Reportable Events.

Minimal Risk Safety Management:

When a study is limited to procedures that are not greater than minimal risk, the Safety Management section of the protocol may be simplified.

# 18 PUBLICATION PLAN

*Research that will not be published does not contribute to generalizable knowledge. This violates the first of*[*Emanuel's requirements for what makes clinical research ethical (link is external)*](http://www.ncbi.nlm.nih.gov/pubmed/10819955)*- namely that the research have social (and scientific value). The plans for publication should be provided as a statement of the investigators assurance that the results will be made public and shared.*

# 19 REFERENCES

*List references here.*