**Research Plan**

**IRB #: \_\_\_\_\_\_\_\_\_\_\_\_\_ CPA #: \_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Section 1: PI Information**

**Study Title:**

**Initial  Revised** *Version Date***:**      

1. **Name of Principal Investigator (PI) & Degree**

**VA Email:       Alternate Email:**

**Phone Number:       Cell Phone Number:       Pager Number:**

1. **Describe the PI’s qualifications to act in the capacity as PI to do the research in this study.**

**Section 2: PI Study Team Information**

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| 1. **Study Coordinator Contact Information**   **Name of Study Coordinator**:  VA **Email:**       Alternate **Email**:  **Phone Number**:        **Cell Phone Number**: |
| **List the PI and personnel who will be assisting in managing the overall study**   |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | | Study Team Member and Degree | Study Role | Access to  Identifiable  data?  (Yes / No) | Obtaining Informed Consent?  (Yes or  No) | Date of Latest VA HSP Training (mm/yy) | Admin Use Only | |  |  |  |  |  |  | |  |  |  |  |  |  | |  |  |  |  |  |  | |  |  |  |  |  |  | |  |  |  |  |  |  |   ***Note: Additional study members may be added by inserting more rows above.***     1. **Does this study involve a designated VA Coordinating Center(s)?** Yes No   If **Yes**, please provide the name of the Coordinating Center(s) and contact information below.  Name of Coordinating Center:  Contact Name (Program Manager or other POC):  Phone Number:       Email address:       @va.gov |

**Section 3: Study Overview**

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| ***1.* What organization is funding this study?** *(Check all that apply)*  VA CSP  VA CSR&D  VA HSR&D  VA RR&D  VA BSLR&D  VA QUERI  VHA Central Office  Private Nonprofit: Please specify:  Commercial Sponsor: Please specify:        Not Funded  Other: Please specify:  2. Definitions- Provide a list of all abbreviations and specialized terms to be used in this document and their definitions:     |  |  | | --- | --- | | Abbreviations / Specialized Terms  (*Use the enter key in this column to insert additional abbreviations and their definitions*) | **Definition** | |  |  | |  |  |   **3. Provide a BRIEF SUMMARY of the background for this research**. DO NOT CUT and PASTE paragraphs that do NOT summarize the background.   * Include a critical evaluation of existing knowledge, and specifically identify the information gaps that your research plan is intended to fill. * Refer to appropriate citations in the scientific literature and include your references at the end of this section. * Include the rationale for conducting the research at the VA.     **4. Provide a BRIEF SUMMARY of the purpose and scientific rationale for this research.** DO NOT CUT and PASTE paragraphs that do NOT summarize the purpose and scientific rationale.   * *State clearly, in terms a non-scientist/non-medical person can comprehend, what you expect to learn from the study and the specific hypothesis (es) to be tested.* * The objectives should be stated in such a way that the reader can determine the appropriateness of the study design     **5. Data Analysis**   * *Provide sample size determination and analysis (include anticipated rate of screen failures, study discontinuations, lost to follow-up etc.).* * *Describe how, where and by whom the data will be analyzed.*     **6. What are the research questions or hypotheses to be studied?**  **7. Describe the relevance to Veterans of studying the above questions or hypotheses and the importance of the knowledge this study is likely to generate:**    **8. The research involves the following procedures conducted by and for what purpose:**   | **PROCEDURE** | **PERFORMED BY:** | | **PROCEDURE IS:** | | | --- | --- | --- | --- | --- | | **Research Staff** | **VANEOHS Clinical or Support Staff** | **Standard of Care\*** | **For Research Purposes Only\*\*** | | **Biopsy** |  |  |  |  | | **Blood collection** |  |  |  |  | | **Chart review – prospective** |  |  |  |  | | **Chart review – retrospective** |  |  |  |  | | **Review of existing data (ex: registry, Database, etc.)** |  |  |  |  | | **X-ray or Ionizing radiation exposure** |  |  |  |  | | **Clinical Tests** |  |  |  |  | | **Device implantation** |  |  |  |  | | **Drug administration** |  |  |  |  | | **EEG, EKG, ECG…etc.** |  |  |  |  | | **Gene therapy, Genetic analysis** |  |  |  |  | | **Pregnancy/Breastfeeding Screening** |  |  |  |  | | **Interview, Questionnaire, Diary, Survey** *(please attach)* |  |  |  |  | | **Stool collection, Urine collection, or any Non-Surgical Specimen collection** |  |  |  |  | | **Surgical procedure or Specimen removal during surgery** |  |  |  |  | | **Tissue banking** *(complete Section 12)* |  |  |  |  | | **Use of pre-existing tissues/specimens** |  |  |  |  | | **Other** *(list)***:** |  |  |  |  |  * *\*Standard of care procedures are procedures performed in the course of normal medical care.* * *\*\*Research Procedures are performed for the purposes of this research alone.*   **9. Please describe the research design and all study related procedures***.*   * *Describe* ***ALL PROCEDURES ASSOCIATED WITH THIS RESEARCH****. This includes standard of care and research procedures.* * *For complex studies please include diagrams and tables. Be sure to describe when each procedure will be performed. Be sure to provide information for* ***each cohort, including normal controls****).*       **10. Does this study involve international research?** Yes  No  ***Note: International research does not include studies in which VA is only one of multiple participating sites where the overall study-wide PI is not a VA investigator.***    **11. Does this study involve collaborative research?** Yes  See below No  If yes, delineate which research activities will be conducted at the VA portion of the overall collaborative research study:    ***Note: Collaborative studies do not include studies conducted under a CRADA with pharmaceutical companies or other for-profit or non-Federal partners.*** |

**Section 4: Potential Risk/Benefit Analysis**

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| **1. Please list by bullet and describe the reasonably foreseeable physical, psychological, social, economic, and privacy risks, side effects, or discomforts associated with the research and their expected frequency and severity. Describe all procedures that minimize risks. Include study and standard of care procedures:**      *If this study is a retrospective chart review, or involves only the analysis of data, risk may still be present in the form of data security concerns.*  **2. Describe alternative procedures or course of treatment, if any, which might be advantageous to the subject. State if no alternatives exist or if this is not a treatment study.**    **Minimal Risk:** Minimal risk means that the risks of harm anticipated in the proposed research are not greater, considering probability and magnitude, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.  **3. Please give your overall risk classification for the research:**  **Minimal Risk**  **Greater than Minimal Risk**  **4. Will subjects receive any direct benefit from this research?**  **No  Yes** -describe the direct benefits**:**  **5. Please explain briefly why you consider the risks associated with the study to be reasonable in relation to its benefits?**    **6. Briefly describe the procedures or explain why there is no need for established procedures for the orderly withdrawal or termination of participation in the study by the participants?**      **7. Will any of the following be administered to participants or will they be exposed to:**  Ionizing Radiation Yes  No  Radioactive Materials Yes  No  \*If yes then Radiation Safety approval required  **10**  **8. Will an independent Data Safety Monitoring Board (DSMB) or a Data Monitoring Committee (DMC) monitor the study?**  Yes  No  If **yes**, provide a description of responsibilities and include frequency of meetings:  **9.**  **Will researchers have access to identifiable private information about potential subjects outside of this research study?** *Ex. PI is provider who has access to medical records for clinical care*  **No  Yes- please explain:** |

**Section 5: Human Participant Information**

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| *Note: A participant is considered “enrolled” at the time the consent is signed so this number should include an allowance for screen failures prior to randomization.*   1. How many records will be reviewed for potential enrollment for each cohort? 2. How many patients will be screened?   Is there a screening consent? Yes  No  3. Estimated number of subjects to be studied at the VA Northeast Ohio Healthcare System or charts/records to be reviewed.   * *Provide answers for each cohort including normal controls; (patients, family members, treating physicians,)*:     4. Estimated number of subjects to be studied or charts/records to be reviewed at all sites   * *Provide answers for each cohort including normal controls; (patients, family members, treating physicians,)*     N/A SINGLE SITE  5. Anticipated duration of entire study reported in years:  6. Duration of individual subject participation  *Provide answers for each cohort including normal controls; (patients, family members, treating physicians,).*  Chart/record review  N/A  7. Does this study target a specific race, gender or ethnic group as participants*?*  Yes  No  If yes, indicate which group and why this group is being targeted*:*  **8. Please describe steps you will take to ensure that subject selection is fair and equitable:**    9. Are any recruitment materials going to be used? Yes  No  If *yes*, list all type of materials that will be used. *If there will be telephonic contact during the recruitment process, a script must be provided and listed below.*   |  | | --- | | Recruitment Material Type | |  | |  | |  |   *Additional* rows *can be added as required.*  *NOTE: All recruitment materials must be reviewed and approved by the IRB prior to use as part of any recruitment activities. All recruitment materials must include a statement that the study involves VA research and a telephone number or other means for the potential participant to use to verify that the study is VA research*  **10. What is the age range of participants?** *(Check all that apply.)*   |  |  |  | | --- | --- | --- | | Specific age range (list age range): |  | | | Adults 18 years or greater |  | | Seniors (Over 65) |  |   **11. Which of the following will be recruited or reviewed for this study** (check all that apply)**?**  Veteran Inpatients  Other  **Veteran Outpatients**  **\*Non-Veterans; If so, Provide justification:**    **\***According to VHA Directive 1605.04 Notice of Privacy Practices VHA must provide a copy of its VHA Notice of Privacy Practices to all non-Veteran subjects. VA Form 10-0483 Acknowledgement of the Notice of Privacy Practices should be signed by the non-Veteran research subject at the time of consent and given a copy of the Notice of Privacy Practices. Once the Acknowledgement Form is signed please send a copy to the Privacy Officer.  12. Does the study target enrollment of any of the following populations or categories of participants?     |  | | --- | | N/A Chart Review | | Employees/students | | Individuals with impaired decision-making capacity | | Pregnant women *(See below)* | | Economically and/or educationally disadvantaged persons | | Prisoners (*See Below)* | | Illiterate, limited, or no English language proficiency (See below) | | Terminally ill patients | | Children (See Below) | | Persons over age 65 |   ***Additional Form Requirement:*** *If prisoners, or pregnant women was checked,**submission of the applicable IRB Form supplements must also be submitted.*  13. Please list by bullet point inclusion/exclusion criteria for the study.   * *Inclusion criteria should be as detailed as necessary to define the subject population(s) under study and reduce confounding design. Include precise criteria for age, gender, and other relevant factors.* * *List specific exclusion criteria which could interfere with the study design or place a subject at risk during the study.* * *Provide answers for each cohort, including normal controls.*     N/A Chart/data review  14. Are any subjects excluded on the basis of race, ethnic group, understanding of English, socioeconomic status, education, gender, or pregnancy?   * *Note: It is appropriate to indicate that you do not anticipate encountering potential subjects who do not speak English based on the population to be studied*   **No  Yes -** *(provide justification)***:**  N/A Chart/data review |

**Section 6: Informed Consent**

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| 1. **Will documented informed consent be obtained from subjects?**   **Yes**  **No**  **2. Will the study involve requesting any waiver or alteration of the consent process or a waiver of documentation of consent for any part of the study?**  **Yes** *See below* **No**  **If yes, check one or more of the following boxes and submit the applicable waiver request(s)*.***   |  |  | | --- | --- | |  | Waiver of informed consent for the entire study. | |  | Waiver of informed consent for recruitment purposes only if one of the following conditions are met:  The Investigator will obtain information through oral or written communication with the prospective subject and the proposed plan is acceptable, **or**  The Investigator will obtain identifiable private information or identifiable biospecimens by accessing records or stored identifiable biospecimens. | |  | An alteration of the informed consent process *Note: If deception is involved this box should be checked.* | |  | Waiver of informed consent for only a specific portion(s) of the study (not including recruitment).  ***Specify for what portion(s) of the study the request is being submitted****:* | |  | Waiver of documentation of informed consent. ***Specify for what portion(s) of the study the request is being submitted****:* |   ***Additional form requirement:*** *IRB Form waiver or alteration of the informed consent process and/or IRB Form waiver of documentation of the informed consent process. Include* ***all*** *portions of the study for which the specific waiver is being requested on the applicable form.*  *If no informed consent is obtained, skip to section 7.*  **3. Will all adult subjects have the capacity to give informed consent?**  **Yes  No- Describe range of impairment.**   * *Research involving more than minimal risk, capacity should be determined by a psychiatrist, clinical psychologist, or other qualified professional not otherwise involved in the research.* * *Individuals who lack the capacity to consent may participate in research only if a legally authorized representative gives consent on their behalf.*     **4. Will anyone other than the subject be authorized to provide consent or permission for the subject’s involvement in the research?**   * *e.g., parents, court ordered guardian, spouse, etc.*   **No  Yes -**please explain**:**  **5. Describe how and where informed consent will be obtained:**    **6. Will there be an opportunity for potential subject to take the consent form home to discuss participation and options with family members?**  **Yes  No -** please explain**:**  **7. List by role who will be obtaining informed consent from subjects or their legally authorized representatives:**        **8. Does the study propose the use of assent for participants unable to give informed consent?**  **N/A**  **Yes** *See below*  **No**  If yes, describe the process for obtaining assent and the procedure followed if the participant  dissents**:**        **9. Does the study involve photos, videos or voice recordings of a VA participant that are done for research purposes?**    **Yes** *See below* **No**  ***Note: If yes, this must be covered in the informed consent process and documented consent documents (consent form, information sheets, telephone screen scripts and HIPAA)*** |

**Section 7: HIPAA Authorization for Study Participants**

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| ***NOTE: Written HIPAA authorization signed by the individual to whom the information or record pertains is required when VA health care facilities need to utilize individually-identifiable health information for a purpose other than treatment, payment, or health care operations, e.g., research. (VHA Directive 1605.1).***   1. **Check all of the following that apply if Protected Health Information (PHI) will be used.**   **If more than one box is checked, specify the part or phase of the study to which the specific checked boxes apply:**   |  |  | | --- | --- | |  | A study specific HIPAA Authorization is combined with the informed consent document. | |  | A separate study specific participant HIPAA Authorization form (VA Form 10-0493) is attached. *Note: This is highly recommended when enrolling individuals with impaired decision making or with longitudinal studies requiring reconsent* | |  | A request for a HIPAA Waiver of Individual Authorization is attached to cover the entire study. | |  | A request for a HIPAA Waiver of Individual Authorization for recruitment purposes only is attached. | |  | A request for a HIPAA Waiver of Individual Authorization is attached to cover a portion of the study. ***Specify portion of study***: |   ***Additional forms requirement:***   * *For requesting a HIPAA waiver, submit IRB Form, Request for Waiver of HIPAA Authorization.* * *When using a separate model HIPAA authorization form, submit VA Form 10-0493, Authorization for Use & Release of Individually Identifiable Health Information for Veterans Health Administration (VHA) Research.* * *In addition, VA Form 10-10116, Revocation of Authorization for Use & Release of Individually Identifiable Health Information for Veterans Health Administration (VHA) Research, can also be submitted if desired.* |

**Section 8: Payment to Participants**

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| 1. Will participants receive compensation in this study? Yes  No   (If ***no*,** skip this section and go to Section 9.)   1. **Indicate the method and mode of payment as follows:** 2. **What form of payment will be used, i.e., check, voucher, electronic funds transfer, cash, debit or gift card?** 3. **What is the amount and schedule of payments, i.e., one-time or after specific visits?**      1. **Provide justification that the proposed payments are reasonable and commensurate with the expected contributions of the participant to the study:**      1. **Does the payment include transportation costs? Yes**  **No** *See below*   **If no, will transportation costs be paid separately**? **Yes**  **No**   1. **Specify the source of payment:**   VA  Cleveland VA Medical Research & Education Foundation  Other (specify):   1. Will an SSN be requested and/or used in making payment/compensation? Yes  No   ***Note: If yes, be sure and include in the HIPAA authorization and in the informed consent the name of the organization making payment to include any VA-affiliated Non-profit Corporation or other non-VA entity.*** |

**Section 9: Biological Specimens**

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| 1. **Will biological specimens be used in this protocol?**   Yes  If specimens will be saved for duration of the study where will they be stored?  NoIf ***no***, skip this section and go to the next.)   1. **List the specimens that are being collected and indicate the purpose of the collection** *(one or both boxes may be checked.)*  |  |  |  | | --- | --- | --- | | **Type of specimens** | **Research Use** | **Clinical Use** | |  |  |  | |  |  |  |   *Additional rows may be added as required.*   1. **Respond to the following questions by checking the appropriate box:**   **YES NO**   |  |  |  | | --- | --- | --- | | a. Does the study involve genetic testing*? If yes, see below:* |  |  | | 1. Does this include whole genome sequencing? |  |  | | 1. Will participants be informed of the results of any DNA testing? |  |  | | 1. Will specimens be kept for future use in other studies? *If yes, see question 7 below.* |  |  | | c. Will samples be made anonymous to maintain confidentiality?  ***Note: Coding data is not considered making it anonymous.*** |  |  | | d. Will specimens be destroyed after the study-specific use is completed? |  |  | | e. Will specimens be used for commercial profit? *If yes, see below:* |  |  | | If yes, will participants share in this commercial profit? |  |  | | f. Will participants be informed of the results of the specimen testing? |  |  | | g. Are there any implications for family members based on specimen testing results? *(If yes, the family members may be participants.)* |  |  |  1. **Will specimens be de-identified?**   Yes No  If ***yes***, describe how the data will be de-identified, who will do it, and at what point in the process will the specimens be de-identified.   1. **What measures will be taken to minimize the potential for physical, psychological, financial, social, or legal harm from breaches of confidentiality and privacy resulting from unauthorized access to or loss of the specimens?** 2. **Describe how the destruction of samples will be carried out:**      1. **If specimens are to be banked for future use in other studies,** indicate where the tissue will be banked. |

**Section 10: Privacy, Confidentiality, and Information Security in Research**

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| 1. **What type of data will be received by the Principal Investigator/Study Chair study team?**   *Check all that apply:*  **De-identified** – Data does not contain any identifiers that could link the data to a specific participant. *(See VHA Directive 1605.01, Appendix B, para 2b, for a list of identifiers that must be removed before data can be considered de-identified. Data must be de-identified in accordance with HIPAA and Common Rule criteria. Scrambling of names and social security numbers is not considered de-identified information.*  **Identified** – Data contains direct identifiers sufficient to identify participants as indicated in VHA Directive 1605.01, Appendix B, para 2b.  **Coded** – Data linked to a specific subject by a code rather than a direct identifier. While the data may contain some protected health information only someone possessing the code can link the data to a particular participant.  **List study team members who will have access to the code by their study role, not by name.**   1. **Indicate how the PHI will be obtained by checking one or more of the boxes below:**   From existing sources such as medical records, clinical databases, or research records.   |  | | --- | | Database Name | |  |   Additional *rows may be added as required.*  Directly from study participants during study procedures as described elsewhere in this application or in the research plan.   1. **Check which of the following HIPAA identifiers will be collected and recorded during the course of the study:**  |  |  |  | | --- | --- | --- | | Names | Social security numbers or scrambled SSNs ***(See below)*** | Device identifiers and serial numbers | | E-mail addresses | Medical record numbers | URLs (Universal Resource Locator) | | All elements of dates (except year) and any age over 89  *Specify:* | Health plan beneficiary numbers | IP Addresses (Internet Protocol | | Telephone numbers | Account numbers | Biometric Identifiers including finger and voice print | | Fax numbers | Certificate or license numbers | Full face photographic images and comparable images | | All geographic subdivisions’  smaller than a state  *Specify:* | Vehicle ID and serial numbers including license plate numbers | Other unique identifying number, characteristic, or code  *Specify:* |  1. **Will a non-VA entity have access to VA sensitive data?** Yes  See below No      1. If ***yes***, specify each entity and identify their roles in the study:      |  |  | | --- | --- | | Name of Non-VA Entity | Role in Study | |  |  | |  |  | |  |  |   *Additional rows may be added as required.*   1. Will there be a Data Use Agreement (DUA) or a CRADA.   Yes  No  If yes, then provide a copy with this application.   1. **List the study team members by title who will have access to the data. *(Specify approximate number of personnel and their job categories, e.g., 2 Co-investigators, 4 Nurse Coordinators, etc.)***      1. **Will specially obtained software be used?** Yes  *See below* No   If ***yes***, describe the software, the source of the software, whether a license will be required and who will fund the license, as well was any data that will be stored in temporary files on the computer’s hard drive.     1. **Will any web-based applications be used?** Yes  *See below* No   If ***yes***, identify the application and its security features. Indicate how it will be used, e.g., for recruiting subjects, completing questionnaires, or processing data.     1. **Will mobile/portable devices be used in the study, i.e., laptops, audio recorders, thumb drive, or portable drives?**   Yes  *See below* No  Are devices issued by VA? Yes  No  Explain  Mobile devices must be encrypted with encryption that is FIPS 140-2 validated.  What type of devices will be used?   1. **How will data be transmitted and/or shipped from and/or to the VA, and how will it be protected during transmission or shipping?** 2. **How will study research data be stored?** 3. Indicate precisely where electronic and/or paper data will be stored to include physical site, drive/folder name (e.g. S: Research/Cardiology), type of mobile storage device, building and room number etc.   ***Note: If data will reside on a non-VA server or non-VA equipment, specify that the server is certified and accredited as required by the Federal Information Security Management Act of 2002 (FIMSA) and that the required permissions for use of a non-VA server have been obtained. Contact your facility’s Information System Security Officer (ISSO) for more information.***   1. If VA sensitive information is being stored outside the protected VA environment, the following questions must be answered:  N/A 2. How are the data being protected? 3. Indicate what VA information will be returned to the VA, how the information will be returned, and/or the plans for its eventual destruction at the alternate non-VA site.      1. **How long will the research data be stored and describe how the data will be destroyed once the maximum retention period as specified by the VHA Records Control schedule or the indicated retention period, if longer, is met?**   In accordance with VHA RCS 10-1, data will be destroyed 6 years after the end of the fiscal year in which the study is closed. Medical Center Policy 136-011 Records Management will be followed.  Other  Please specify:   1. **What is the plan for protecting study research data from improper use or disclosure?** *As part of the response to this question, indicate that removal of access to research study data will be accomplished for study personnel when they are no longer part of the research team. Include that the ISSO and Privacy Officer will be notified within one hour of the improper use or disclosure.*        1. **Will a Certificate of Confidentiality (CoC) be obtained?**   Yes  No  *If* **yes***, include this information in the informed consent form.*  ***Note: If this is a qualifying NIH Study, the CoC will be assumed. A CoC helps investigators protect the privacy of human research participants enrolled in biomedical, behavioral, clinical and other forms of sensitive research. Certificates protect against compulsory legal demands, such as court orders and subpoenas, for identifying information or identifying characteristics of a research participant.* *For more information on CoCs go to:*** [***http://grants.nih.gov/grants/policy/coc/***](http://grants.nih.gov/grants/policy/coc/)**.**   1. **Will data be disclosed (copy given) outside of VHA?**   Yes  See *below* No  If ***yes***, describe to whom the data are to be disclosed, the justification for such disclosure, and the authority for the disclosure, e.g., HIPAA authorization or VA Form 10-5045, Request for and Authorization to Release Medical Records or Health Information.     1. **Will data be banked for re-use in future studies?** Yes  *See below* No      1. Where will the data be banked?   Name of entity:       Location:   1. This is an existing data repository with appropriate oversight mechanism per VHA Directive 1200.12. Yes  No   This is a non-VA entity, are the appropriate safeguards addressed in the CRADA or Data Use Agreement?    Yes  No |

**Section 11: FDA-Regulated and Other Products**

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| 1. **Does the study use drugs, biologics, supplements, or devices?**   Yes  No  (**If No, skip to Section 12)**   1. **Indicate the type of clinical trial if applicable?**   Phase I  Phase II  Phase III  Phase IV   1. **Does the study involve an Investigational New Drug Application (IND) or Investigational New Device Exemption (IDE), Abbreviated IDE, or IND Exception?**   Yes  *See below* No  If ***yes***, attach a copy of any applicable correspondence with the FDA and complete the following:  a. Indicate the name of the person or organization holding the IND or IDE, if applicable:  b. Is there a plan for onsite data monitoring?  Yes  *See below* No  If ***yes***, ***specify*** who will conduct monitoring responsibilities and how often:     1. **How will FDA-regulated products used in this study be dispensed and tracked to participating sites?**      1. **If using FDA-regulated drugs or biologics, indicate use:** N/A  |  |  | | --- | --- | |  | Investigational or Unapproved Drug(s) or Biologics (Attach a copy of the FDA’s acknowledgement letter stating that FDA received the IND application.) | |  | Approved Drug(s) or Biologics For Approved Uses | |  | Approved Drug(s) or Biologics for Unapproved Uses (Use will be inconsistent with product labeling or involves a new use, labeling, advertising change, or a change in dose, dosage form, administration schedule, or recipient) |  1. **List all drugs, biologics, or supplements to be used below.** *Check here if N/A:*  |  |  |  |  |  | | --- | --- | --- | --- | --- | | Generic Name | Trade Name | Manufacturer | Use Consistent with Product Labeling?  Yes/No | IND Number if Applicable | |  |  |  |  |  | |  |  |  |  |  |   *Add additional rows to table if necessary*  a. Is an Investigator’s brochure included with the application materials?  Yes  No  If no, please indicate why?  b. For all approved drugs used for an unapproved use, describe the unapproved use**:**  N/A    c. If an IND is not required, explain and/or provide sponsor or FDA documentation**:**  N/A     1. Attach VA Form 10-9012 Investigational Drug Information Record for each drug used in the protocol 2. Attach Package Insert or PDR monograph – copy ready, 8.5 x 11 for each drug listed in the protocol 3. **If using FDA-regulated devices, indicate use:**  N/A      |  |  | | --- | --- | |  | Investigational or Unapproved Device(s) | |  | Approved Device(s) for an Approved Use | |  | Approved Device(s) for an Unapproved Use | |  | Other *(e.g., humanitarian use device; 510k clearance) Specify:* |  1. **List the FDA-regulated devices that will be used.** N/A  |  |  |  |  |  | | --- | --- | --- | --- | --- | | Name | Manufacturer | Use Consistent w/ Product Labeling?  Yes, No, or N/A | Significant Risk (SR) or Non-Significant Risk (NSR), Unknown, or N/A | IDE Number if Applicable | |  |  |  |  |  | |  |  |  |  |  | |  |  |  |  |  |   a. If this is a non-significant risk device study, is documentation attached with the application materials explaining the manufacturer’s or a sponsor’s determination why the device is not a Significant Risk (SR) device?*(See 21 CFR 812)*  Yes  No  N/A  b. If applying for an IDE, a copy of the dated IDE application letter to the FDA is included with this submission.  N/A |

**Section 12: Request for Expedited Review**

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| 1. **Check the below boxes as applicable for this study. All three boxes must be checked in order for the study to qualify for expedited review:**   The study presents no more than minimal risk to participants.  The identification of participants or their responses will not reasonably place them at risk of criminal or civil liability or be damaging to their financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal.  The study is not classified.   1. **If all three boxes are checked above, indicate one or more categories below for which this study would qualify for expedited review:**   Category **1:** Clinical studies of drugs and medical devices only when one of the following conditions is met.  **1a:** An investigational device exemption application (21 CFR Part 812) is not required.  **1b:** The medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.  **Category 2:** Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:  **2a:** From healthy, non-pregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8-week period and collection may not occur more frequently than 2 times per week.  **2b:** From other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8-week period and collection may not occur more frequently than 2 times per week.  **Category 3:** Prospective collection of biological specimens for research purposes by noninvasive means.  **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.  **Category 5:** Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for non-research purposes (such as medical treatment or diagnosis). This category also includes research involving materials that were previously collected for either non-research or research purposes, provided that any materials collected for research were not collected for the currently proposed research.  **Category 6:** Collection from voice, video, digital or image recordings made for research purposes.  **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.  ***If the study does not fit into one of the above categories, it does not qualify for expedited review*** |

**Section 13: Contents of Application (Check all documents included in this package)**

***\*Asterisk indicates a mandatory document for all studies. Indicate additional forms submitted***

**Research Plan\***

Investigator’s Drug Brochure

Investigator Device Information

Participant Instructions

Recruitment Materials

Informed Consent Form

Questionnaires or Surveys

VA Investigational Drug Information *(VA Form 10-9012*)

PDR Monograph or Package Insert

Request for Waiver of Documentation of Informed Consent

Investigator’s Phone/Video Scripts

Request for Waiver or Alteration of Informed Consent Forms/etc.

Request for HIPAA Waiver of Individual Authorization Study Application Supplement

Separate HIPAA Authorization

Data Collection Forms/Tools/Case Report

Exemption Request Form

List any other documentation included in this package: *(e.g., Certificate of Confidentiality, Data Use Agreements, DMC charter, etc.)*

**Section 14: Principal Investigator Statement**

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| **As the Principal Investigator for this study, I certify that I have read, understand, and accept the investigator responsibilities as outlined in VHA Directive 1200.05, paragraph 5g and that these include but are not limited to the following:**   * Giving first priority to the protection of human subjects; upholding professional and ethical standards and practices; and adhering to all applicable VA and other Federal requirements, include IRB and the local VA Facility’s policies and procedures regarding the conduct of research and the protection of human subjects. * Ensuring all investigators and other staffs participating in this human subject’s research are qualified; have the appropriate training, education, and experience to perform procedures assigned to them; and that they have been appropriately credentialed and privileged as applicable per current local facility and VA requirements. * Submitting all amendments to the study or changes in the informed consent to the IRB for review and approval prior to initiation, except when necessary to eliminate immediate hazard to the participants. Any changes implemented as a result of an immediate hazard will be promptly reported to the IRB as a study deviation and an amendment submitted if determined necessary. * Obtaining and documenting legally effective informed consent of the subject or the subject’s legally authorized representative (LAR), as well as a HIPAA authorization, unless the IRB approves an applicable waiver. * Reporting problems, adverse events, and apparent serious or continuing noncompliance, including local research deaths, in accordance with VHA Directive 1058.01, local VA Facility requirements, and IRB SOPs (to include the IRB Table of Reporting Requirements.) * Ensuring appropriate research records are maintained that includes all information made or received by a VA Investigator over the entire lifecycle of the research activity and that these records are maintained in accordance with the VA Records Control Schedule and local policies and procedures. * Providing continuing review and/or requested updates for the study as applicable in a timely manner and in accordance with the VA and IRB policies and procedures. This includes submission of a closure reports for both local sites and the overall study upon completion. noncompliance. * Ensuring research does not start until final approval has been received from the IRB, and written notification from the local Facility ACOS/R&D in accordance with local R&D Committee approval policies and procedures.  |  |  |  | | --- | --- | --- | |  |  |  |   Principal Investigator/Signature Date |