Veterans Affairs
[INSTITUTION NAME]
IRB Information Sheet

Header Information - This information is automatically populated at the top of the form.
Last edited by: [User]
Last edited on: [Date]
IRBNet ID and Project Title

1. **PAGE: Introduction**
   This IRB Information Sheet must be completed for all applications submitting to an internal or external IRB.

   To request a determination of exemption from the requirements of 38 CFR 16, first complete the Exemption Request Form (2.0A), then complete this VA – IRB Information Sheet only if your institution's IRB performs exempt determinations. Check with your research office for additional guidance.

   The data in this form are used for reporting purposes and must be kept accurate and up to date.
   Any proposed changes after IRB approval require submission and approval of a modification request (amendment).
   (No Response)

2. **PAGE: Non-VA IRB**
   Are you submitting to a Non-VA IRB?
   (Radio Buttons)
   a. Yes
   b. No

3. **PAGE: Multi-site** – *This PAGE will only appear if "Non-VA IRB: No" is selected.*
   Is this a multi-site project? Note: multi-site project is defined as a study with more than one site participating in human subjects research.
   (Radio Buttons)
   a. Yes
   b. No

4. **PAGE: Local Site Investigator –** *This PAGE will only appear if Multi-site: Yes" is selected.*
   Are you a local site investigator submitting to the VA Central IRB?
   a. Yes
   b. No

5. **PAGE: Local Site Investigator Application –** *This PAGE will only appear if "Local Site Investigator: Yes" is selected.*

a. **Site-Specific Differences**
Please select from the following topics where there are differences between your site's activity and what the PI had indicated in their application.

Please select all that apply.
(Checkboxes)

i. Subject populations
ii. Recruitment strategy - [Please upload all new recruitment materials that have been created as part of your site's recruitment strategy.]
iii. Modifications in recruitment materials (other than local contact information) – [Please upload all recruitment materials that were modified for your site from the PI's approved templates (beyond updating local contact information)]
iv. Modifications to the Informed Consent Form template - [Please use the Microsoft Word track changes function to indicate modifications in the ICF provided by the PI/SC. Upload BOTH tracked and untracked versions of the documents]
v. Modifications to HIPAA authorization documents - [Please upload copies of the modified HIPAA authorization documents that are specific to your site.]

b. **Site-Specific Explanation**
Please explain the reasons for each of the differences that you have described above.
(Rich Text Response)

6. **PAGE: PI Assessment of Risk Level -** *This PAGE will NOT appear if "Local Site Investigator: Yes" is selected*
Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. Greater than minimal risk means that the research procedures may include risk beyond what is ordinarily encountered by subjects (e.g. maximal exercise testing, experimental drugs, invasive procedures, biologics or medical devices, stressful psychological testing, use of special populations).
IRB makes final assessment of risk level.
(Radio Buttons)
   a. Greater than Minimal Risk
   b. Minimal Risk

7. **PAGE: Minimal Risk Review Type Requested** – *This PAGE will only appear if "PI Assessment of Risk: Minimal Risk" is selected.*
(Radio Buttons)
   a. Determination of Exemption (Exemption Request Form 2.0A – completed)
   b. IRB Expedited Review
   c. Convened IRB Review as study does not meet either Exempt or Expedited criteria

8. **PAGE: Greater than Minimal Risk Review Type Requested** - *This PAGE will only appear if "PI Assessment of Risk: Greater than Minimal Risk" is selected.*
   (Radio Buttons)

   i. IRB
   ii. Emergency Use of an Investigational Product – Single IND
   iii. Non-Emergency Use of an Investigational Product to convened IRB (Expanded Access/IND) single patient intermediate access treatment

9. **PAGE: Exemption Category Information** – *This PAGE will only appear if "Minimal Risk Review Type Requested: Determination of Exemption (Exemption Request Form 2.0A – completed) is selected".*

   a. **Exemption Category**
      Based on the Exemption Request Form (2.0A) you completed:
      (Checkboxes)
      i. Category 1
      ii. Category 2 (i/ii)
      iii. Category 2 (iii)
      iv. Category 3i (A/B)
      v. Category 3i (C)
      vi. Category 4 (i)
      vii. Category 4 (ii)
      viii. Category 4 (iii)
      ix. Category 4 (iv)
      x. Category 5
      xi. Category 6
      xii. Category 7
      xiii. Category 8

   b. All **Activities Involved Fall Within Exemption Categories** – *This FORM will end if the user selects No.*
      (Radio Buttons)
      i. Yes
      ii. No – STOP – this protocol cannot be reviewed as exempt. You must change your answer to question 3 – Review Type Requested to IRB.

10. **PAGE: Expedited Categories** - *This PAGE will only appear if "Minimal Risk Review Type Requested: IRB Expedited Review" is selected.*
    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.

Select all expedited categories that apply:
(Checkboxes)

i. Category 1a
ii. Category 1b
iii. Category 2a
iv. Category 2b
v. Category 3
vi. Category 4

vii. Category 5
viii. Category 6
ix. Category 7

b.

11. **PAGE: Lead Site Name** – *This PAGE will only appear if "Non-VA IRB: No" is selected AND "Multi-site: Yes" AND "Local Site Investigator: No" is selected.*
    If there is a lead site, which site is the Lead site? If there is no lead site, please enter "N/A".
    (Plain Text Response)

12. **PAGE: Coordinating Centers** – *This PAGE will only appear if "Non-VA IRB: No" AND "Local Site Investigator: No" is selected.*
    Is there a coordinating center separate from the lead site?
    (Radio Buttons)
    a. Yes
    b. No – the lead site operates as the coordinating center
    c. N/A – No coordinating center

13. **PAGE: Coordinating Center Name** - *This PAGE will only appear if "Non-VA IRB: No" AND "Local Site Investigator: No" is selected AND "Coordinating Center: Yes" is selected.*
    What is the coordinating center site?
    (Plain Text Response)

14. **PAGE**: **Clinical Trial** – *This PAGE would NOT appear if "Local Site Investigator: Yes" is selected. Clinical trial means a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of the interventions on biomedical or behavioral health-related outcomes.*

    Is this a clinical trial?
    (Radio Buttons)
    a. Yes
    b. No

15. **PAGE: Investigational Drug Study** – *This PAGE will only appear if "Clinical Trial: Yes" is selected.*
    Is this an investigational drug study? A substance that has been tested in the laboratory and has been approved by the U.S. Food and Drug Administration (FDA) for testing in people.
    (Radio Buttons)
    a. Yes
    b. No

16. **PAGE: Clinical Trial Information** - *This PAGE will only appear if "Clinical Trial: Yes "is selected.*

    a. **Clinical Trial Phase**

Phase 0 – Phase 0 trials are also known as human micro-dosing studies and are designed to speed up the development of promising drugs or imaging agents by establishing very early on whether the drug or agent behaves in human subjects as was expected from preclinical studies.
Phase I – Phase I includes the initial introduction of an investigational new drug into humans. These studies are closely monitored and may be conducted in patients but are usually conducted in healthy volunteer subjects.
Phase II – Phase 2 includes the early controlled clinical studies conducted to obtain some preliminary data on the effectiveness of the drug for a particular indication or indications in patients with the disease or condition.
Phase III – Phase 3 studies are expanded controlled and uncontrolled trials. They are performed after preliminary evidence suggesting effectiveness of the drug has been obtained in Phase 2, and are intended to gather the additional information about effectiveness and safety that is needed to evaluate the overall benefit-risk relationship of the drug.
Phase IV - Studies conducted after the intervention has been marketed. These studies are designed to monitor the effectiveness of the approved intervention in the general population and to collect information about any adverse effects associated with widespread use.
(Radio Buttons)

i. Phase 0
ii. Phase I
iii. Phase I/II
iv. Phase II
v. Phase III
vi. Phase IV

b. **ClinicalTrials.gov Number** - *This response is optional.*
When available, please enter the ClinicalTrials.gov Number.
(Plain Text Response)

c. **Data Safety Monitoring Board**
Is there a Data Safety Monitoring Board (DSMB) for this study?
(Radio Buttons)

i. Yes
ii. No – If No, Submit the DSMB charter

17. **PAGE: International Research Information** – *This PAGE will only appear if "Non-VA IRB: No" is selected and the researcher indicated that they are not a local site investigator submitting to the CIRB.*
    a. **Sites Outside the US**

Does this project involve any sites outside of the United States (US), its territories, or Commonwealths) – NOTE: Research conducted at U.S. military installations, ships, or embassies is not considered outside the United States?
(Radio Buttons)

i. Yes [A medical center director letter will be required for this international research project]
ii. No

b. **Data or Specimens Originating from Outside the US**
Are any data or specimens in this study originating from outside the United States (US) its territories, or Commonwealths) – NOTE: Research conducted at U.S. military installations, ships, or embassies is not considered outside the United States?
(Radio Buttons)

i. Yes
ii. No

c. **Data or Specimens From Research Being Sent**
Are any data or specimens from this research being sent out of the United States (US), its territories, or Commonwealths) – NOTE: Research conducted at U.S. military installations, ships, or embassies is not considered outside the United States?
(Radio Buttons)

i. Yes
ii. No

18. **PAGE: VA as the Lead Site –** *This PAGE will only appear if "Non-VA: No" is selected AND selects "Yes" to any question on the PAGE "International Research Information".*

Is the VA the lead site or coordinating center for this study?
(Radio Buttons)

a. Yes – If yes, this study is international research in accordance with 1200.05 and a Medical Center Director letter is required for the coordinating center and/or lead site.
b. No – Even though international work is occurring, this study is not considered international research by VHA policy.

19. **PAGE: International Research Description** - *This PAGE will only appear if "Non-VA: No" is selected AND "VA as Lead Site: Yes" is selected.* Briefly describe the international research.
(Rich Text Response)

20. **Subject Population Information –** *This PAGE will only appear if "Local Site Investigator: No" OR "Local Site Investigator Application: Subject populations" is selected.*
(Checkboxes)

a. **Subject Populations Requiring Special Considerations**
i. None

ii. VA Employees in their VA capacity [You will need to coordinate with Labor and Management Relations]
iii. Students, Residents, and/or Fellows [The protocol must describe how undue influence is being avoided with the students/residents and/or fellows]
iv. Pregnant Women or Neonates [Certification by the Medical Center Director will be required for interventional studies or invasive monitoring of pregnant women as subjects]
v. Persons with acute or chronic Impaired Decision-Making Capacity
vi. Non-veterans (including family members and caregivers) [You will need to submit 3.5A Request for Non-Veteran Approval]
vii. Family Members and/or Caregivers
viii. Non-English Speakers [You will need a translation, if using an ICF/Information sheet]
ix. Prisoners [Letter of support from Medical Center Director will be required. VHA Directive 1200.05 requires a CRADO waiver for inclusion of prisoners. Waiver request must be submitted to vhacoordregulatory@va.gov by the Medical Center Director with the required documentation as described in the Directive]
x. Children (Determined by state/territory/commonwealth age of majority)
xi. Other

b. **Subject Populations – Other** - *This response is optional.*
If you selected "Other", describe.
(Plain Text Response)

21. PAGE: Subject Groups Information - *This PAGE will repeat for every Subject Group.*

Note: A participant is considered "enrolled" at the time the consent is obtained so the total number needed to reach the number required to complete the study should include an allowance for screen failures prior to randomization and study drop-outs. Where appropriate answer 0 or N/A.

a. **Description of Subject Group**
(Rich Text Response)

b. **Age Range**
Note: If neonates or children is checked, certification by the Medical Center Director will be required to complete the study should include an allowance for screen failures prior to randomization and study drop-outs.
i. Neonates (Less than 1 month of age)
ii. Children (Determined by state/territory/commonwealth age of majority)
iii. Adults

c. **Subject Group - Informed Consent**
CHECK ALL THAT APPLY.
(Checkboxes)

i. Informed Consent will be obtained from subjects or subject's legally authorized representatives (LAR) and documented with a signed, written consent form
ii. A Waiver or Alteration of Informed Consent will be requested (An alteration of consent is where consent will be obtained but one or more of the elements of consent will be excluded or altered) [Submit Application for Waiver/Alteration of ICF]
iii. A Waiver or Alteration of Documentation of Consent will be requested (A waiver of documentation of consent is where consent will be obtained but a written consent form will not be used) [Submit Application for Waiver/Alteration of Documentation of ICF]

d. **Collection of Health Information**
CHECK ALL THAT APPLY.
(Checkboxes)
i. Yes, data which will be accessed are de-identified or constitute a limited data set (LDS)
ii. Yes, subject's authorization will be obtained
iii. Yes, a waiver of authorization will be requested
iv. No

e. **Subject Group – HIPAA Authorization**
CHECK ALL THAT APPLY.
(Checkboxes)
i. HIPAA Authorization will be sought from each individual or the subject's personal representative.
ii. A partial waiver of HIPAA Authorization will be sought. (Submit Application for Waiver of HIPAA Authorization])
iii. A waiver of HIPAA Authorization is being sought (Submit Application for Waiver of HIPAA Authorization]

f. **Records Accessed in Advance**
Will records (electronic health record, paper records, etc..) be accessed to identify potential subjects for recruitment or for screening purposes?
(Radio Buttons)
i. Yes [Submit Application for Waiver of HIPAA Authorization]
ii. No

g. **Number of Records of Accessed** – *This response is optional.*
If yes, how many records will be accessed?
(Plain Text Response)

h. **Participants Enrolled**
How many participants do you plan to enroll to meet your study objectives?

(Plain Text Response)

i. **Screening Procedures After Enrollment** – *This response is optional.*
If applicable, please describe any further screening procedures after enrollment.
(Rich Text Response)

22. PAGE: Recruitment Strategy Information – *This PAGE will only appear if "Non-VA IRB: No" is selected. This PAGE will only appear if "Local Site Investigator: No" OR "Local Site Investigator Application: Recruitment strategy" is selected.*
Indicate which of the following methods will be used to conduct recruitment at your site. Check all that apply. *NOTE: Copies of any proposed flyers, posters, pamphlets, print advertisements, scripts for on-air advertisements or phone calls, web listings, etc. must be submitted with your application.*
NOTE: VA policy prohibits "cold calls" to potential VA research participants. Initial contact must be made in person or by letter prior to making any telephone contact, unless there is written documentation that the subject is willing to be contacted by phone about the specific study or the specific kind of research. The initial telephone contact must also provide a telephone number or other means for the potential participant to use to verify the study constitutes VA research (VHA Handbook 1200.05).

a. **Recruitment Strategy**
   i. CPRS/Medical records
   ii. Flyers/Posters/Handouts
   iii. Newspaper/Magazine Adds
   iv. Radio/Television
   v. Letters (to potential subjects, providers, colleagues, etc.)
   vi. Phone Calls (NOTE: "Cold" calling may not be used as a recruitment method)
   vii. In Person
   viii. Social Media
   ix. Other

b. **Recruitment Strategy – Other** – *This response is optional.*
If you selected Other, please describe:
(Plain Text Response)

23. PAGE: Pregnant Women Subjects Information - *This PAGE will only appear if "Subject Populations: Pregnant Women, Fetuses, or Neonates" is selected.*

a. **Pregnant Woman - Focus of Research**
Are pregnant women, human fetuses, or neonates the focus of the research?
(Radio Buttons)
   i. Yes

ii. No

b. **Pregnant Women - Risks**
Is the study greater than minimal risk (will there be any interventions or invasive monitoring that includes risk)?
(Radio Buttons)
i. Yes
ii. No

c. **Pregnant Women - Greater than Minimal Risk**
Are there any other study procedures that involve greater than minimal risk? This does not include clinical follow-up of women who become pregnant while on a study and are withdrawn from the intervention portion of the study with follow-up of the pregnant women neonates for safety and outcome purposes.
(Radio Buttons)
i. Yes
ii. No

24. PAGE: Pregnant Women Subjects Information Continued - *This PAGE will only appear if "Yes" was selected on any of the previous questions on the "Pregnant Women Subjects Information" PAGE.*

a. **Preclinical Studies Including Pregnancy**
Where scientifically appropriate, have preclinical studies including studies on pregnant animals and clinical studies including studies on non-pregnant women, been conducted and do they provide data for assessing potential risks to pregnant women and fetuses? *A description of such studies should be included in the project application.*
(Radio Buttons)
i. Yes [A description of preclinical studies including studies on pregnant animals and clinical studies including non-pregnant women should be included in the project application.]
ii. No

b. **Risk to Fetus**
Is the risk to the fetus caused solely by interventions or procedures that hold out the prospect of direct benefit for the woman or the fetus; or, if there is no such prospect of benefit, is the risk to the fetus not greater than minimal and is the purpose of the research to develop important medical knowledge which cannot be obtained by any other means?
(Radio Buttons)
i. Yes
ii. No

c. **Benefit to Pregnant Women**

If the research holds out the prospect of direct benefit to the pregnant woman, the prospect of a direct benefit both to the pregnant woman and the fetus, or no prospect of benefit for the woman nor the fetus when the risk to the fetus is not greater than minimal and the purpose of the research is the development of important biomedical knowledge that cannot be obtained by any other means, is the pregnant woman's informed consent obtained in accordance with the informed consent provisions of VHA Directive 1200.05?
(Radio Buttons)

i. Yes
ii. No

d. **Informed Consent for Pregnant Women**
Is each individual providing informed consent fully informed regarding the reasonably foreseeable impact of the research on the fetus? For children who are pregnant, are assent and permission obtained in accordance with the provisions of 45 CFR Part 46, Subpart D?
Note: Research involving clinical interventions with the potential of greater than minimal risk cannot be conducted by VA investigators on children who are pregnant.
(Radio Buttons)

i. Yes
ii. No

e. **Possibility of Risks**
Is any risk the least possible for achieving the objectives of the research?
(Radio Buttons)

i. Yes
ii. No

f. **Inducements in Terminating Pregnancy**
Are there inducements included in the research, monetary or otherwise, that will be offered to terminate a pregnancy?
(Radio Buttons)

i. Yes
ii. No

g. **Decisions Used to Terminate Pregnancy**
Will individuals involved in the research have part in any decisions as to the timing, method, or procedures used to terminate a pregnancy?
(Radio Buttons)

i. Yes
ii. No

h. **Viability of Neonate**

Will individuals engaged in the research have any part in determining the viability of a neonate?
(Radio Buttons)

i. Yes
ii. No

i. **Protections and Safeguards for Pregnant Women**
Describe any additional protections and safeguards in the protocol for the use of pregnant women, human fetuses and neonates.
(Rich Text Response)

25. **PAGE: Category of Permissible Prisoner Research** - *This PAGE will only appear if "Subject Populations: Prisoners" is selected.*

Category 1: The research is minimal risk and no more than an inconvenience to the participants. It involves the possible causes, effects, and processes of incarceration and of criminal behavior.

Category 2: The research is minimal risk and no more than an inconvenience to the participants. It involves a study of prisons as institutional structures or of prisoners as incarcerated persons.

Category 3: The research is a study on conditions particularly affecting prisoners as a class, i.e., social and psychological problems such as alcoholism and drug addiction.

Category 4: The research is a study on practices, both innovative and accepted, which have the intent and reasonable probability of improving the health and/or wellbeing of the participants.

Category 5: This is an epidemiologic study. The sole purpose of the project is to describe the prevalence or incidence of a disease or condition by identifying all cases or to study the potential risk factors associated with a disease or condition. The research presents no more than minimal risk and no more than an inconvenience to the participants. Prisoners are not a particular focus of the research.

Category 6: The research involves a project participant that became incarcerated after enrollment in the project. It is to the benefit of the project participant to remain enrolled in the project.

a. **Permissible Prisoner Categories**
The investigator should check the appropriate box below to indicate the category of permissible prisoner research to which the study pertains.

(Checkboxes)

i. Category 1
ii. Category 2
iii. Category 3

iv. Category 4
v. Category 5
vi. Category 6

b. **Benefits for Permissible Prisoners** - *This response is optional.*
If Category 6 is checked, indicate below why it is to the benefit of the participant to remain in the study and include whether this continued participant has been coordinated with applicable prison officials.
(Rich Text Response)

26. PAGE: Prisoners Information - *This PAGE will only appear if "Subject Populations: Prisoners" is selected.*

a. **Prisoners - Possible Advantages**
Are there any possible advantages to the prisoner from his/her participation in the research when compared to the general living conditions, medical care, quality of food, amenities, and opportunity for earnings in the prison that would impair the participant's ability to weigh the risks of the research against the value of such advantages?
(Radio Buttons)
i. Yes
ii. No

b. **Prisoners - Risks Involved in Research**
Are the risks involved in the research commensurate with the risks that would be accepted by non-prisoner volunteers?
(Radio Buttons)
i. Yes
ii. No
iii. N/A

c. **Prisoners - Procedures for Subject Selection**
Are procedures for selection of participants within the prison fair to all prisoners and immune from arbitrary intervention by prison authorities and are these procedures described in the protocol?
(Radio Buttons)
i. Yes
ii. No
iii. N/A

d. **Prisoners - Control Groups**
If control groups are going to be used, will the control participants be randomly selected?
(Radio Buttons)
i. Yes

ii. No
iii. N/A – No control group

e. **Prisoners - Research Information**
Please explain how you think the information presented is in a language understandable to the general prison population?
(Rich Text Response)

f. **Prisoners - Informed Consent**
Does the informed consent document clearly state that participation in the research will not affect parole decisions and has the investigator trained prison authorities in this requirement?
(Radio Buttons)
i. Yes
ii. No

g. **Prisoners - Protections and Safeguards** - *This response is optional.*
If there is a need for follow-up examinations or care of participants after the end of their participation in the research and, if so, has adequate provision been made for such examinations or care considering the length of the individual prisoner sentences. Note: These provisions must be described in the protocol.
(Rich Text Response)

27. PAGE: Non-English Speaker Information - *This PAGE will only appear if "Subject Populations: Non-English Speakers" is selected.*

a. **Language of Participants**

What is the language of the participants to be enrolled at that site?

(Rich Text Response)

b. **Certified Translation of Informed Consent**

Is a certified translation of the informed consent document available in the language(s) of the potential non-English speakers? Note: If so, it must be attached.

(Radio Buttons)

i. Yes

ii. No

c. Plan for Obtaining Consent
How do you plan to obtain informed consent from the non-English speakers and to maintain ongoing communication, if applicable, with the Non-English speaker throughout the study?
(Rich Text Response)

28. **PAGE: Non-Veterans including Family Members and/or Caregivers** *This PAGE will only appear if "Subject Populations: Non-Veterans" is selected.*

    a. **Non-Veterans Including Family Member and/or Caregivers**
    If there is the possibility that the non-Veteran might be hurt in the research study is there a plan in the protocol, and is it described in the consent form, how research related injury will be handled?
    (Radio Buttons)
        i. Yes
        ii. No

    b. **Non-Veterans Including Family Member and/or Caregivers Explanation -** *This response is optional.*
    If no please describe.
    (Rich Text Response)

29. **PAGE: Children** *This PAGE will only appear if "Subject Populations: Children" is selected*
    a. **Children Assent**
    Will assent be obtained from the child participants?
    (Radio Buttons)
        i. Yes
        ii. No

    b. **No Children Assent**– *This response is optional.*
    Provide justification as to why the assent of the child will not be obtained from the child participants?
    (Rich Text Response)

30. **PAGE: Person with Impaired Decision-Making Capacity** *This PAGE will only appear if "Subject Populations: Persons with Impaired Decision-Making Capacity" is selected*
    a. **Impaired Decision-Making -**
    How will the capacity for consent be determined for those potential participants who may have impaired decision-making capability?
    (Rich Text Response)

    b. **Legally Authorized Representative Consent**
    Will a Legally Authorized Representative (LAR) be sought to obtain consent?
    (Radio Buttons)
        i. Yes
        ii. No

    c. **Plan to Seek Consent**
    Does the protocol include a plan to seek consent from the subject should he/she regain capacity?
    (Radio Buttons)
        i. Yes

ii. No

d. **Plan to Seek Consent – Explanation** – *This response is optional.*
If you selected "No", please explain.
(Rich Text Response)

e. **Plan to Seek Ongoing Consent**
Is there a plan to seek ongoing consent from the LAR should the patient lose capacity during the study and new risk/benefit data are discovered?
i. Yes
ii. No
iii. N/A

f. **Plan to Seek Consent – Explanation** – *This response is optional.*
If you selected "No", or "N/A", please explain.
(Rich Text Response)

31. **PAGE: Intended Participants** – *This PAGE will only appear if "Non-VA IRB: No" AND if "Local Site Investigator: No" OR "Local Site Investigator Application: Subject populations" is selected.*
Does the project target a specific race, ethnicities/ethnic group or gender?
(Radio Buttons)
i. Yes
ii. No

32. **PAGE: Participants Information -** *This PAGE will only appear if "Non-VA IRB: No" is selected AND "Intended Participants: Yes" is selected.*

a. **Intended Race and/or Ethnicities**
What is the intended race of the participant group? Check all that apply.
(Checkboxes)
i. N/A – no specific race is being intended
ii. American Indian or Alaskan Native
iii. Asian or Asian American
iv. Black or African American
v. Caucasian
vi. Native Hawaiian or Other Pacific Islander
vii. Hispanic or Latin American
viii. Unknown
ix. Other

b. **Intended Race and/or Ethnicities - Other** - *This response is optional.*
If you selected "Other", state the Race/ethnicities below.
(Plain Text Response)

c. **Ethnic Group Intended**
Is a specific ethnic group intended for research participation?
(Radio Button)
   i. Yes
   ii. No

d. **Ethnic Group Intended – Explanation -** *This response is optional.*
If you selected "Yes", please describe.
(Plain Text Response)

e. **Intended Gender**
Check all that apply.
(Checkboxes)
   i. N/A – not targeting a specific gender
   ii. Male
   iii. Female
   iv. Other – for transgender studies

33. **PAGE: Participant Compensation** – *This PAGE will only appear if "Non-VA IRB: No" is selected, ANDif "Local Site Investigator: No" OR "Local Site Investigator Application: Participant Compensation" is selected.*
NOTE: If applicable, the method (and relative amounts) of payment should be the same at all participating sites whenever possible. Local Site Investigators will be asked to provide justification to the IRB for differences in method and/or relative amounts.

Will participants receive compensation in this study?
(Radio Buttons)
   i. Yes
   ii. No

34. PAGE: Participant Compensation Details - *This PAGE will only appear if "Non-VA IRB: No" is selected AND "Participant Compensation: Yes" is selected***.**

a. **Form of Payment**
What form of payment will be used, i.e., check, voucher, electronic funds transfer?
(Plain Text Response)

b. **Schedule and Amount of Payments**
What is the schedule of payments, i.e., one-time or after specific visits? Please provide total amount of payment that any participant may receive.
(Plain Text Response)

c. **Justification for Proposed Payments**

Provide justification that the proposed payments are reasonable and commensurate with the expected contributions of the participant to the project:
(Rich Text Response)

35. **PAGE: Research Procedures Information** – *This PAGE will only appear if "Local Site Investigator: No" OR "Local Site Investigator Application: Research Procedures" is selected.*

    a. **Research Procedures**
    Check all that apply.
    (Checkboxes)
        i. Establishment of a data repository
        ii. Use of data from a data repository
        iii. Contribution of data to an external data repository (registries)
        iv. Establishment of a specimen (tissue) repository
        v. Use of stored/purchased specimen (tissue)
        vi. Contribution of specimen (tissue) to a specimen (tissue) repository
        vii. Drugs, biologics, or supplements
        viii. Medical devices
        ix. Ionizing radiation
        x. Genetic testing
        xi. Non-embryonic stem cells
        xii. Clinical procedure(s)
        xiii. Surgical procedure(s)
        xiv. Medical record review only
        xv. Observation of subjects/others(e.g., caregivers)
        xvi. Questionnaires/surveys (Note: Scripts and questions must be included with submission) [Scripts and questions must be included with submission]
        xvii. Interviews (Note: Must be included with submissions) [Interviews must be included with submission]
        xviii. Audio-recording/video-recording/photos
        xix. Usual care/standard of care
        xx. Other
        xxi. Humanitarian Use Device

    b. **Research Procedures - Other** - *This response is optional.*
    If you selected "Other", please specify.
    (Plain Text Response)

36. **PAGE: Questionnaires/Surveys Information** - *This PAGE will only appear if "Research Procedures: Questionnaires/surveys" is selected.*

    a. **Questionnaire/Survey Method of Distribution/Administration**
    (Checkboxes)
        i. Telephone

ii. Mail
iii. Email
iv. Virtual (Webex/Teams, etc…)
v. In person
vi. Other

b. **Questionnaire Type - Other** - *This response is optional.*
If you selected "Other", please specify.
(Plain Text Response)

37. PAGE: VA Data or Tissue Repository Information – *This PAGE will only appear if "Research Procedures: Establishment of data repository" OR "Research Procedures: Establishment of a specimen (tissue) repository" OR "Research Procedures: Contribution of specimen (tissue) to a specimen (tissue) repository" is selected.*

a. **VA Repository Storage Location**
Where will the data be stored?
(Radio Buttons)
i. VA Facility
ii. Non-VA Facility

b. **VA Repository Storage Location Point of Contact**
Please provide a point-of-contact for the facility where the repository will be located.
(Plain Text Response)

c. **Identifiable Data**
Will data be identifiable?
(Radio Buttons)
i. Yes
ii. No

d. **Identifiable Information and De-Identification Description**
Please describe the identifiable information that will be included (if any), and the procedure for de-identification of data before inclusion in the repository (if applicable).
(Rich Text Response)

e. **Committee Overseeing Repository**
If the data is stored at a VA facility, what IRB (for identifiable data) or R&D Committee (if de-identified) is responsible for overseeing the data repository?

If the data is stored at a non-VA facility, please enter "N/A."
(Plain Text Response)

38. **PAGE: Drugs, Biologics or Supplements Information** - *This PAGE will only appear if "Research Procedures: Drugs, biologics, or supplements" is selected. This PAGE will repeat for every Drug, Biologic, or Supplement entered.*
Please complete this section for each Drug or Biologic.

    a. **Type**
    (Drop-down menu)
        i. Drug
        ii. Biologic
        iii. Supplement

    b. **Trade Name of Drug/Biologic/Supplement**
    Please provide the trade name of the drug, biologic, or supplement.
    (Plain Text Response)

    c. **Manufacturer Name**
    (Plain Text Response)

    d. **Generic Name**
    Please provide the generic name of the drug or biologic or N/A.
    (Plain Text Response)

    e. **IND #**
    If this is not applicable (such as if this is a supplement), please enter “N/A”.
    (Plain Text Response)

    f. **IND Holder**
    If this is not applicable (such as if this is a supplement), please enter “N/A”.
    (Plain Text Response)

    g. **Plan for On-Site Data Monitoring**
    Is there a plan for FDA required on-site data monitoring?
    (Radio Buttons)
        i. Yes
        ii. No

    h. **On-Site Data Monitoring Responsibilities**
    Please describe if the sponsor will be contracting with a CRO or who will perform the responsibilities in reporting to the FDA.
    (Rich Text Response)

    i. **Investigator Brochure or Package Insert Included**

Is an investigator brochure or package insert included with the application materials?
(Radio Buttons)

i. Yes
ii. No

39. **PAGE: Brochure Not Included** - *This PAGE will only appear if "Investigator Brochure Included: No" is selected for at least one Drug, Biologic, or Supplement.*
Describe why an investigator brochure is not included.
(Rich Text Response)

40. **PAGE: Device Information** - *This PAGE will only appear if "Research Procedures: Medical Devices" is selected. This PAGE will repeat for each Medical Device***.**
Please complete this section for each Medical Device.

a. **Device Trade Name or N/A**
(Plain Text Response)

b. **Device Generic Name or N/A**
(Plain Text Response)

c. **Device Manufacturer Name**
(Plain Text Response)

d. **IDE #**
(Plain Text Response)

e. **IDE Holder**
(Plain Text Response)

f. **Device Type of Use**
Is this a new investigational device, or is this a device being used for a new indication?
(Radio Buttons)

i. New investigational device
ii. Approved device for new indication
iii. Approved device for approved use

g. **Device Class**
https://www.fda.gov/about-fda/cdrh-transparency/overview-medical-device-classification-and-reclassification
(Plain Text Response)

h. **Manufacturer Device Information**

Is manufacturer's device information (i.e. device manual/technical manual) included with the application material?
(Radio Buttons)

i. Yes
ii. No

i. **Explanation for No Manufacture Information** - *This response is optional.*
If no, describe why the manufacturer's device information is not included
(Rich Text Response)

j. **Device Risk Assessment**
Do you have a device risk assessment (significant risk or non-significant risk) from the FDA or the manufacturer?
(Radio Buttons)

i. Yes – [You indicated that you have a device risk assessment for one or more of the medical devices involved in the project. Please include the assessment(s) in your submission.]
ii. No

41. **PAGE: Usual Care/Standard of Care in a Clinical Space**
Does the project involve usual care/standard of care in combination with study procedures?
(Radio Buttons)

i. Yes
ii. No

42. **PAGE: Certificate of Confidentiality**
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/.

Will a Certificate of Confidentiality be obtained or applied for?
(Radio Buttons)

i. Yes [Include Certificate of Confidentiality information in the informed consent form]
ii. No

43. **PAGE: Humanitarian Use Device** – *This PAGE will only appear if "Research Procedures: Humanitarian Use Device" is selected.*

a. **HUD Device Trade Name**
Enter N/A if not applicable.
(Plain Text Response)

b. **HUD Device Generic Name**
Enter N/A if not applicable.
(Plain Text Response)

c. **HUD Device Manufacturer Name**
(Plain Text Response)

d. **HDE Number**
(Plain Text Response)

e. **Manufacturer Device Information and FDA HDE approval letter**
Is the manufacturer's product labeling, clinical brochure, and/or other device information (i.e. device manual) and FDA HDE approval letter included with the application material?
(Radio Buttons)
   i. Yes
   ii. No

f. **Explanation for No Manufacturer Information –** *This RESPONSE is optional.*
If the manufacturer's device information is not included with the application material, please describe why.
(Rich Text Response)

44. PAGE: Form Complete

Thank you for completing the **VAIRRS IRB Application**.

Additional required documentation:
[SMART LIST]

- Submit the DSMB charter *Appears when "Data Safety Monitoring Board: No" is selected.*
- A medical center director letter will be required for this international research project *Appears when "Sites Outside the US: Yes" is selected.*
- You will need to coordinate with Labor and Management Relations *Appears when "Subject Populations Requiring Special Considerations: VA Employees in their VA capacity" is selected.*
- The protocol must describe how undue influence is being avoided with the students/residents and/or fellows *Appears when "Subject Populations Requiring Special Considerations: Students, Residents, and/or Fellows" is selected.*

- Certification by the Medical Center Director will be required for interventional studies or invasive monitoring of pregnant women as subjects *Appears when "Subject Populations Requiring Special Considerations: Pregnant Women or Neonates" is selected.*
- You will need to submit 3.5A Request for Non-Veteran Approval *Appears when "Subject Populations Requiring Special Considerations: Non-veterans (including family members and caregivers)" is selected.*
- You will need a translation, if using an ICF/Information sheet *Appears when "Subject Populations Requiring Special Considerations: Non-English Speakers" is selected.*
- Letter of support from Medical Center Director will be required. VHA Directive 1200.05 requires a CRADO waiver for inclusion of prisoners. Waiver request must be submitted to vhacoordregulatory@va.gov by the Medical Center Director with the required documentation as described in the Directive. *Appears when "Subject Populations Requiring Special Considerations: Prisoners" is selected.*
- Submit Application for Waiver/Alteration of ICF *Appears when "Subject Group – Informed Consent: A Waiver of Alteration of Informed Consent will be requested (An alteration of consent is where consent will be obtained but one or more of the elements of consent will be excluded or altered) is selected.*
- Submit Application for Waiver/Alteration of Documentation of ICF *Appears when "Subject Group – Informed Consent: A Waiver or Alteration of Documentation of Consent will be requested (A waiver of documentation of consent is where consent will be obtained but a written consent form will not be used)" is selected.*
- Submit Application for Waiver of HIPAA Authorization *Appears when "Subject Group – HIPAA Authorization: A partial waiver of HIPAA Authorization will be sought OR A waiver of HIPAA Authorization is being sought" OR "Records Accessed in Advance: Yes" is selected.*
- A description of preclinical studies including studies on pregnant animals and clinical studies including non-pregnant women should be included in the project application.] *Appears when Preclinical Studies Including Pregnancy: Yes" is selected.*
- Scripts and questions must be included with submission *Appears when "Research Procedures: Questionnaires/surveys (Note: Scripts and questions must be included with submission)" is selected.*
- Interviews must be included with submission *Appears when "Research Procedures: Interviews (Note: Must be included with submissions)" is selected.*
- You indicated that you have a device risk assessment for one or more of the medical devices involved in the project. Please include the assessment(s) in your submission. *Appears when "Device Risk Assessment: Yes" is selected.*
- Include Certificate of Confidentiality information in the informed consent form *Appears when "Certificate of Confidentiality: Yes" is selected.*