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| **Study Information** |

If requesting an Exemption, please submit the ***Exemption from VDSS IRB Review Request Form***.

Study Title: **Click here to enter text.**

State the purpose(s) of research, 100 words or less: **Click here to enter text.**

Is this research funded or supported by a U.S. federal department or agency? **Choose an item.**

If federal funding, provide the name of federal department/agency: **Click here to enter text.**

Is the research supported by a grant or contract? Yes No Partial Funding

Has another IRB reviewed, declined to review, tabled, deferred, disapproved, suspended, or terminated this study? Yes No

In what form and to whom will the results of your study or activities be released? **Click here to enter text.**

Indicate the subject group(s) that will be recruited or about whom PII will be collected or accessed (Select all that apply):

Adults  Children (less than 18 years)  Pregnant Women  Prisoners

Other vulnerable populations (specify): **Click here to enter text.**

Number of Adults to be enrolled **Click here to enter text.**

Number of children to be enrolled **Click here to enter text.**

Investigator’s assessment of study risk to prospective subjects

Minimal Risk Greater than Minimal Risk

Planned implementation date: **Click here to enter a date.**

Planned study end date: **Click here to enter a date.**

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| **Primary Funder Information** |

Prefix **Choose an item.** Contact Full Name (Last, First, MI): **Click here to enter text.**

Degree(s) **Click here to enter text.**

Organization **Click here to enter text.**

Mailing Address Line 1 **Click here to enter text.**

Mailing Address Line 2 **Click here to enter text.**

City **Click here to enter text.** State Choose an item.Zip Code **Click here to enter text.**

Email: **Click here to enter text.** Phone: **Click here to enter text.**

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| **Principal Investigator Information** |

Prefix **Choose an item.** PI Full Name (Last, First, MI): **Click here to enter text.**

Degree(s) **Click here to enter text.**

Organization **Click here to enter text.**

Mailing Address Line 1 **Click here to enter text.**

Mailing Address Line 2 **Click here to enter text.**

City **Click here to enter text.** State Choose an item. Zip Code **Click here to enter text.**

Email: **Click here to enter text.** Phone: **Click here to enter text.**

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| **Other Study Contact** |

Prefix **Choose an item.** Full Name (Last, First, MI): **Click here to enter text.**

Degree(s) **Click here to enter text.**

Organization **Click here to enter text.**

Mailing Address Line 1 **Click here to enter text.**

Mailing Address Line 2 **Click here to enter text.**

City **Click here to enter text.** State Choose an item. Zip Code **Click here to enter text.**

Email: **Click here to enter text.** Phone: **Click here to enter text.**

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| **Investigator and Research Personnel History** |

Has the principal investigator, any co-investigators, any sub-investigators, or any research personnel been issued any of the following - At any time in the past: NIDPOE (Noticed of initiation of Disqualification Proceedings and Opportunity to Explain); Suspension by a federal or governmental agency (such as FDA, HHS, or termination by an IRB, FDA Warning Letter); OHRP Determination Letter, or conviction of a crime?

**No Yes;** If yes, submit all related documents including resolution steps.

Has the principal investigator, any co-investigators, any sub-investigators, or any research personnel ever had any of the following: denied, revoked, suspended, reduced, limited, placed on probation, not renewed, relinquished, sanctioned, fined, or subject to disciplinary action?

Research privileges at any site; professional society memberships or fellowship/board certification; professional sanctions including fines and public reprimands.

**No Yes;** If yes, submit all related documents including resolution steps.

Is any action or investigation currently pending before any state licensing board, federal agency, or court of law concerning the professional conduct of the principal investigator in her/his capacity as a research investigator?

**No Yes;** If yes, submit all related documents including resolution steps.

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| **Financial Interest Disclosure** |

Do you, or any of the other research personnel, or your immediate families, have any of the following financial interests in the sponsor, product or service being tested?

- With regard to any publicly traded entity, a significant financial interest exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure and the value of any equity interest in the entity as of the date of disclosure, when aggregated, exceeds $5,000. For purposes of this definition, remuneration includes salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship); equity interest includes any stock, stock option, or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value; - With regard to any non-publicly traded entity, a significant financial interest exists if the value of any

remuneration received from the entity in the twelve months preceding the disclosure, when aggregated, exceeds $5,000, or when the Investigator (or the Investigator’s spouse or dependent children) holds any equity interest (e.g., stock, stock option, or other ownership interest); or

- Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.

**Yes  No**

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| **Training and Experience** |

Indicate the types of training that you and your research staff have had on the protection of human research subjects during the most recent three years. Select all that apply.

Collaborative IRB Training Initiative (CITI)  OHRP Training Modules

NIH Protecting Human Research Participants Course  Local Institution's Training

SOCRA Clinical Research Professional (CRP)  Investigator Meeting(s)

Other IRB training (specify): Click or tap here to enter text.

None, identify study personnel not trained Click or tap here to enter text.

Does the PI have more than one year of human subject research experience?  Yes  No

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| **Subject Recruitment** |

How will subjects be recruited for this study? Select all that apply.

Advertisements  Telephone Screening Scripts

Referrals  Use of PII, no subject recruitment

Other, please describe: **Click here to enter text.**

N/A

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| **Consent Process** |

Indicate the setting for the consent process. Select all that apply.

N/A, a complete waiver of consent is requested  Group setting

Group setting with follow-up in a private room  Private room

Online, in public, or over the phone  Exempt Review

Other, please describe: **Click here to enter text.**

Indicate the measures that will be taken during the consent process. If you do not select both items, explain why below.

The person conducting the consent process will spend the time needed to thoroughly explain and respond to questions potential subjects and/or their legally authorized representative have about the study, and

Potential subjects will be allowed as much time as needed to adequately read and consider the consent form, and to decide whether or not to enroll in the study.

Explain Consent Process: **Click here to enter text.**

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| **Consent Information** |

How you are planning to provide consent information to potential subjects? Select all that apply.

Long form consent document  Short form consent document and summary

Script or information sheet (a Request for Waiver of Informed Consent is requested)

What is the expected duration of the subject’s participation? Describe: **Click here to enter text.**

What research procedures are subjects expected to follow? Describe: **Click here to enter text.**

Does the study include any experimental procedures?  No Yes – describe below

Experimental procedures: **Click here to enter text.**

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| **Subject Payment for Participation** |

Will subjects be paid, reimbursed or receive a stipend for participation?  Yes  No

What is the amount of each payment? **Click here to enter text.**

How many payments and when will subjects receive payment? (e.g., monthly, quarterly, after each visit, etc.) **Click here to enter text.**

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| **Translations** |

Will translated version(s) of the subject information and consent form be needed to facilitate a subject’s understanding of the research study?  Yes  No  N/A

List the documents that need translation (e.g., informed consent forms, recruitment materials, information sheets). **Click here to enter text.**

If you are enrolling non-English speaking subjects, you must have plans for conducting the consent discussion and other subject interactions. Below, check all that apply:

At least one member of the research team is fluent in the language that will be used for communication, and that research staff member(s) will be available when needed as a translator.

The research team has 24-hour access to a translation service with sufficient expertise to discuss the research in this study.

Other, please describe: **Click here to enter text.**

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| **Confidentiality** |

Confidentiality refers to the agreement between the investigator(s) and subjects in how data will be managed and used. Indicate the procedures that you will follow to maintain the confidentiality of data collected about the subject. Select all that apply.

Training of research personnel Study staff will sign confidentiality agreements

Storage of paper records in a secure location accessible only to research personnel

Coding of data with separate storage of the key and coded data

NIH Certificate of confidentiality

Removal of identifiers as soon as possible, state when identifiers will be removed

Describe additional confidentiality procedures: **Click here to enter text.**

Will confidential data be stored on desktop computers?  **Yes  No  N/A**

Will confidential data be stored on mobile devices (e.g., laptops, tablets, cell phones)?

**Yes  No  N/A**

Will confidential data be stored on removable media (e.g., USB/thumb drives, removable hard drives, CD)?  **Yes  No  N/A**

Will confidential data be transmitted over the Internet?  **Yes  No  N/A**

Describe other methods that will be used to transfer/transmit confidential information **Click here to enter text.**

Describe the disposition of identifying information (method and intended time frame).**Click here to enter text.**

Describe how your organization will maintain the confidentiality of the identifying information. **Click here to enter text.**

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| **Privacy** |

Privacy refers to persons’ interest in controlling the access of others to themselves, such as the ability to control who sees them, hears them, touches them, and has access to their private information. Additional privacy interests include the time and place where subjects provide information, the nature of the information provided by the subjects, the nature of the subjects experiences during the trial, and who receives and can use the information.

What procedures will you follow to protect the privacy of the subject? Select all that apply.

The consent process will be performed in a private setting

Research procedures will be performed in a private setting

Private information collected will be limited to that necessary to conduct the research

Other, specify: **Click here to enter text.**

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| **Study Risks/Benefits** |

The IRB is responsible for evaluating the potential risks and weighing the probability of the risk occurring and the magnitude of harm that may result. The type of harm can be physical, psychological, legal, social, and/or economic. The benefit of a study can be to the participant in the study and/or the general community. The researcher is obligated to disclose potential risks and benefits to study participants as part of the consent process.

List the potential risks to study participants **Click here to enter text.**

List potential benefits to study participants **Click here to enter text.**

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| **Protocol Abstract** |

Summarize the study protocol or project activities. Indicate specifically the way data will be collected and used. No more than 300 words. **Click here to enter text.**

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| **Investigator Agreement** |

ACKNOWLEDGEMENT

The investigator submitting this form shall promptly communicate or provide the following information relevant to the protection of human subjects to the VDSS IRB in a timely manner:

a. Any site monitoring report that directly and materially affects subject safety or their willingness to continue participation. Such reports will be provided to the IRB within 5 days.

b. Reports from any data monitoring committee, data and safety monitoring board, or data and safety monitoring committee in accordance with the timeframe specified in the Study protocol.

c. Any findings from a closed study when those findings materially affect the safety of past subjects. Findings will be reported for 2 years after the closure of the study.

d. Provide to the VDSS IRB an abstract documenting study results (§32.1-162.19), as soon as practicable.

e. Report to the VDSS IRB any Unanticipated Problems, including protocol deviations.

By submitting this form, I am confirming that I am the Principal Investigator (PI). The information within this form is accurate and complete with the PIs full awareness of the information submitted.

I agree

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| PI Signature (Print) Click or tap here to enter text. | Date Click or tap to enter a date. |

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| **Required Attachments** |

Please submit the following additional documentation with your application

1. Final signed protocol
2. PI curriculum vita (CV) or NIH biographical sketch
3. A copy of the complete grant or contract
4. A detailed explanation of the previous review(s) by other IRB(s)
5. IRB Approval letter, if applicable
6. Request for Waiver of Informed Consent (or documentation of informed consent), if applicable.
7. All information intended to be seen or heard by subjects, including:
   * Consent/Assent documents
   * Information sheets
   * Recruitment scripts
   * Advertisements

Submit electronic copies of this form, along with copies of the project protocol and other supporting documents, to[**irb@dss.virginia.gov**](mailto:irb@dss.virginia.gov?subject=VDSS%20IRB%20Submission). **Questions?** Contact us at [irb@dss.virginia.gov](mailto:irb@dss.virginia.gov).